University of Alberta

Patents on Genetically Modified Animals: A Harvard Mouse case study

by

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A thesis submitted to the Faculty of Graduate Studies and Research
in partial fulfillment of the requirements for the degree of

Master of Laws

Faculty of Law

Edmonton, Alberta
Fall 2008

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Your file Votre référence
ISBN: 978-0-494-47167-8
Our file Notre référence
ISBN: 978-0-494-47167-8

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ABSTRACT

When the Supreme Court of Canada held in *Harvard College v. Commissioner of Patents* that the Harvard- oncomouse, which is a genetically modified mouse to be susceptible to cancer, was unpatentable under the *Canadian Patent Act*, many groups of people were astonished. There was a high expectation that the Court would grant a patent on the oncomouse because other countries such as the United States and European countries already granted a patent on the oncomouse.

After the Supreme Court's decision in *Harvard College v. Canada*, there remain legal and policy problems. This thesis will explain the background of the *Canadian Patent Act* and the creation of the oncomouse, and pertinent interpretation issues under s.2 of the *Patent Act*. Then, the thesis will propose a regulatory framework such as a research and experimental use exception, an innocent bystander defence, a farmer's privilege and 'ordre public' and morality, which should be included within the *Patent Act*. Moreover, *Harvard College v. Canada* shall be applied to Thai patent law. In conclusion, I shall recommend that the oncomouse and similar creations should be patentable subject matters if legislation is amended to incorporate of proposed regulatory framework.

ACKNOWLEDGEMENTS

I would like to thank my thesis supervisor, Professor Wayne Renke, who helps me completing this thesis successfully without his support and his guidance the thesis would not be possible. Second, I also would like to thank the defence committee, Professor Tania Bubela and Professor Moin Yahya. Third, I would like to thank my mother and my father, Rewadee and Thongtong Raktaprachit for their love, supports and encouragement all my life and their love encourages me to reach my goals. Fourth, I would like to thank David O'Sullivan who edited and read all my papers. Fifth, I would like to thank all my teachers who have taught me. Finally, I would like to thank all my friends who help me and go though laughs and cries with me.

Contents

Introduction 1

Chapter1:

History of the *Canadian Patent Act* and the creation of the oncomouse

Introduction 5

1. The History of the *Canadian Patent Act* 5

2. DNA and the invention of the oncomouse 7

3. Patent law and Biotechnology 9

3.1 The Patent Criteria 10

3.2 The Relationship between Patent Law and Biotechnology 11

3.3 *TRIPS* Agreement and the patentability of higher life forms 12

4. Cases about the patentability of genetically modified living organism

4.1 *Diamond v. Chakrabarty* 14

4.2 *Harvard College v. Canada* 15

4.3 *Monsanto Canada Inc. v. Schmeiser* 16

Conclusion 17

Chapter 2: The *Harvard College* decisions and legal issues

Introduction 19

1. The Interpretation of the words "composition of matter" 19

1.1 "Composition" 20

1.2 "Matter" 22

2. The "Laws of Nature" 28

3. "Making" Living Things and "Making" Non-Living Things 31

4. The 'Control' Test 32

5. The Scheme of the *Act* 35

5.1 The majority opinion in *Harvard College* 36

(a) The lack of regulatory framework means that Parliament did not intend to include higher life forms to be patentable subject matter 37

(b) The Court does not have a duty to interpret the Act broader than Parliament's intention 37

5.2 The dissenting opinion 38

(a) The lack of regulatory frameworks does not exclude higher life forms from patentability 39

(b) The Court has a duty to interpret the words of the Act to include unexpected inventions 40

(c) The prohibition of patenting on humans is an example of a regulatory framework outside the *Patent Act* 41

5.3 The analysis of the scheme of the Act 42

(a) The lack of regulatory framework 42

(b) The Court's duty in the interpretation the words of the Act 44

6. The object of the Act 46

6.1 The Majority Opinion on the Object of the Act 46

6.2 The dissent's opinion on the Object of the Act 47

(a) The *Patent Act* does not promote flow of scientific information to society 47

(b) The *Patent Act* does not promote technological advancement 47

6.3 The analysis of the object of the Act 48

(a) The promotion of technology and development 48

(b) The free flow of the scientific information among scientists 49

Conclusion 50

Chapter 3: The *Plant Breeders' Rights Act*

Introduction 51

1. The *Plant Breeders Rights Act* and Breeding Plants and Animals 51

1.1 *The Plant Breeders' Rights Act* 53

1.2 A case about the breeding plants and *sui generis* 54

Pioneer Hi-Bred v. Canada (Commissioner of Patents) 54

2. The majority opinion in the creating the *sui generis* system like the *PBRA* for the oncomouse 56

3. The dissent opinion in the creating a *sui generis* system similar to the *PBRA* for the oncomouse 57

4. The analysis of the *PBRA* 58

Conclusion 61

Chapter 4: Regulatory Frameworks

Introduction 63

1. The regulatory frameworks that prohibits other people from using the patented invention without permission 63

1.1 The Research and Experimental Use Exception (REUE) 63

1.2 The Farmers' privilege 70

1.3 Innocent Bystander Defense 72

2. The additional rules required to prevent immoral patents

The 'ordre public' or morality exception 79

3. The analysis of 'ordre public' and morality exception 85

Conclusion 88

Chapter 5: Thai Patent Law and Biotechnological Inventions

Introduction 89

1. The Evolution of Thai Patent Law 89

1.1 Patentable subject matter under the *Thai Patent Act* 90

1.2 Petty Patent under the *Thai Patent Act* 92

2. The Patentability of Genetically Modified Animals under the Thai Patent Law 94

3. Patents on biological inventions 101

***4. TRIPS Agreement* and Thailand 103**

Conclusion 105

Conclusion 107

Bibliography 110

Introduction

Biotechnology has become an important technology used to explore the mystery of the DNA of living organisms. One reason for the exploration of DNA is to find the cause of serious diseases and how we can treat them. In this regard, genetically modified animals can be used for clinical research.

Due to the advanced development of biotechnology, scientists use recombinant DNA technology to create genetically modified plants and animals. This leads to the use of genetically modified animals for food production and clinical research. However, recombinant DNA technology is a relatively new technology, which was discovered only a few decades ago. Uncertainty about the technology still exists. People fear that the DNA technology will lead to the creation of new species of humans, animals and plants without knowing the exact consequences. This fear also arises when genetically modified animals and plants -including modified genes and cells- have become involved with the intellectual property law such as the Patent laws. Modified genes and cells are now accepted as patentable subject matter in many countries.

Patent law is involved with DNA and genetically modified animals because patent law is intellectual property law which provides protection for any new, useful, and non-obvious invention.[1] As a result, inventions created by biotechnology such as the recombinant DNA technology may be patentable subject matter. This includes modified animals and their modified genes and cells, if the inventions are new, useful, and non-obvious. People are concerned about patents on genetically modified animals. They fear

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[1] ***Patent Act***, R.S.C. 1985, c. P-4, s. 2.

there may be hidden dangers to patents on humans and the human body. Many legislatures affirm that humans and the human body must not be patentable subject matter and pass laws to directly prohibit such patents.

Controversy over the patenting of DNA was sparked when the genetically modified mouse or the oncomouse was patented in the United States in 1988.[2] The Oncomouse (hereafter called the oncomouse), is a mouse which is genetically engineered by recombinant DNA technology to be susceptible to carry a gene which makes the mouse more susceptible to cancer. Such genes are known as "oncongenes." Many groups such as animal rights groups, environmental groups and religious groups oppose any patent on the oncomouse because it is an animal and the issue of animal suffering. Therefore, they maintain it should not be patented. Despite this opposition, the European Union granted a patent on the oncomouse in 1992.[3] Even though the oncomouse was patented in many countries, there is still opposition to its patenting.

In 2002, the Supreme Court of Canada decided in *Harvard College v. Commissioner of Patents (Canada)*[4] that the oncomouse as a higher life form was not patentable subject matter. This decision created multiple problems. One of the main problems with the Court's decision is with the interpretation of the word "composition of matter." The majority of the Supreme Court of Canada determined that the oncomouse did not fall within the word "composition of matter;" therefore, the oncomouse was not an "invention" under s. 2 of the *Patent Act*. On the other hand, the dissent of the Supreme

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[2] Eileen Morin, "Of Mice and Men: The Ethics of Patenting Animals," (1997) 5 Health L.J. 154
[3] *Ibid.*
[4] *Harvard College v. Commissioner of Patents (Canada)* [2002] 4 S.C.R. 45, 2002 S.C.C. 76 [hereinafter cited as *Harvard College*].

Court argued that the oncomouse was a "composition of matter," and it should be patentable subject matter. Furthermore, the majority and the dissent discussed the issue of the interpretation of the word "composition of matter" by comparison with the leading U.S. case, *Chakrabarty*.[5] The main consequence after the *Harvard College* decision is the ability of Canadian patent law to deal with future inventions based on new technology. If a biotechnological invention such as the oncomouse could not be encompassed within patentable subject-matter, there may be difficulties in granting patents over future and unpredictable inventions such as nanotechnological inventions. The decision might have a negative impact on the Canadian economy and Canada's research and development sector. Also, biotechnological companies may be discouraged from investing in Canada if their inventions will not receive patent protection.

To solve the problems arising out of *Harvard College* decision, I will adopt a five-part analysis. In my first chapter, I shall address Parliament's intention implicit in the legislation by focusing on a short history of the Canadian *Patent Act* and the treatment of inventions when the *Patent Act* was enacted and the relationship between patent law and biotechnological inventions. In my second chapter, I shall discuss the legal issues in the *Harvard College* decision from the aspects of both the majority and dissent. I will compare the opinions with precedents in other jurisdictions. I shall conclude whether the oncomouse should be patentable subject matter. In my third chapter, I will discuss whether the *sui generis* system such as the *Plant Breeders' Rights Act* should be applied to the oncomouse. In my forth chapter, I shall propose certain

[5] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) [hereinafter cited as *Chakrabarty*].

legislative changes that will provide a regulatory framework for the patenting of genetically modified animals. The lack of this regulatory framework contributed to the Supreme Court's reluctance to grant a patent on biotechnological inventions. In the fifth chapter, I shall discuss about the Thai patent law and patents on biotechnological inventions.

Chapter 1

The History of *the Canadian Patent Act* and the Creation of the Oncomouse

Introduction

In order to construe the Supreme Court's decision in *Harvard College v. Commissioner of Patents*, the Canadian patent law and the scientific background of the creation of the oncomouse should be studied. I shall separate this chapter into five parts. First I will briefly review the history of the *Canadian Patent Act*. Second, I shall explore DNA and the invention of the Oncomouse. Third, I shall explain the general relationship between patent law and biotechnology. Fourth I shall review cases relating to the patentability of genetically modified animals- *Diamond v. Chakrabarty, Harvard College v. Commissioner of Patents* and *Monsanto v. Schmeiser*. Finally, I shall discuss the three cases in general in the analysis of cases relating to patents on genetically modified animals.

1. History of the *Canadian Patent Act*

In order to study the history of the Canadian patent law, British and U.S. law should be taken into account. The Canadian *Patent Act* is adopted from the provisions of these two jurisdictions. However, Canada tends to have patent legislation more similar to the U.S. statute rather than that to British patent law.

Originally, Canada might have granted a patent by prerogative authorization similar to that of England.[6] However, there is no evidence as to how the patent system worked in Canada prior to 1792.[7]

Canadian patent law dates back to the Statute of Lower Canada of 1823, which was based principally on the U.S. *Patent Act*.[8] The Statute provided exclusive rights for a patentee in making, constructing, using and selling an invention. A patent was to be granted to inventors of "any arts, machine, manufacture, or composition of matter invented by them."[9] In 1826, the *Patent Act* was enacted in Upper Canada with similar language.[10] Subsequent to Confederation in 1867, the first federal *Patent Act* of 1869 was enacted by the federal legislature to replace both previous Acts.[11] The *Patent Act* of 1869, however, relied heavily on the *Patent Act* of the United States of 1836. The *Patent Act* of 1869 was the foundation of the current *Patent Act* of 1985.[12] Nevertheless, Canada did not accept the whole concept of the U.S. statute.[13] In particular, in 1989, Canada abandoned the U.S. concept of giving priority to the first inventor and used the concept of 'first to file' system as in other countries.[14] The abandonment of the U.S. approach to patents is more obvious after Canada did not grant a patent on the Oncomouse.

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[6] Harold G. Fox, *Monopolies and Patents: A Study of The History and Future of The Patent Monopoly* (Toronto: The University of Toronto Press, 1947) at 193.
[7] *Ibid.*, at 193.
[8] *Ibid.*, at 248. Lower Canada is now the province of Quebec.
[9] *Ibid.*
[10] *Ibid.* Upper Canada is now the province of Ontario.
[11] William L. Hayhurst, "The Intellectual Property Laws in Canada: The British Tradition, The American Influences, and The French Factors," (1996) 10 I.P.J. at 275.
[12] *Ibid.*
[13] *Ibid.*
[14] *Ibid.*

2. DNA and the invention of the Oncomouse

In the early 1980s, the first genetically modified mice and fruit flies were invented.[15] The invention of the oncomouse was created from the modification of genes of the mouse using recombinant DNA technology. To understand the genetically modified mouse, an understanding of the structure of DNA is important.

In 1953, James Watson and Francis Crick discovered the "double helix," which is the structure of deoxyribonucleic acid (DNA).[16] DNA is called "the blueprint of life" since it contains the genetic code which identifies the characteristics of every organism.[17] The "double helix" is the two strands of DNA, each of which contains a nucleic acid polymer.[18] If the two strands are separated, each strand, which is the sequence of the composition of nucleotides, will link to another nucleotide in another strand to form a 'double helix.' The match between two strands is called 'nucleotide base pairing' or 'nucleotide base complementarity.'[19] For example, the Adenine base matches with the Thymine base, while the Guanine base matches with the Cytosine base. [20] DNA is the most important composition of a gene.[21] Each gene is a series of the instructions to form a single protein.[22] Proteins are important in functioning living organisms because they

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[15] National Human Genome Research Institute, "1981-1982: First Transgenic Mice and Fruit Flies (13 March 2008), online: National Human Genome Research Institute <http://www.genome.gov/pfv.cfm?pageID=25520307> [hereinafter cited as "First transgenic mice]. Last visit: 13 March 2008.

[16] Thomas Trian Moga, "Transgenic animals as intellectual property (or the patented mouse that roared)," (1994), J. Pat. & Trademark Off. Society, at 522.

[17] Morin, *supra* note 2 at 149

[18] Moga, *supra* note 16 at 522.

[19] *Ibid.*

[20] *Ibid.*, at 523.

[21] Mark Jagels, "Dr. Moreau has left the island: dealing with human-animal patents in the 21st century," (2001) 23 T. Jefferson L. Rev. at 119.

[22] *Ibid.*, at 120.

create structure, catalyze biochemical pathways, establish the immune system, and digest food.[23]

Not only are genes the inherited characteristics passed from parents to the next generation, they could be modified to acquire wanted genes by various techniques known as 'recombinant DNA technology,' generally referred to as genetic engineering.[24] The techniques used in genetic engineering include "microinjection, cell fusion, electroporation, and retroviral transformation."[25] Among these techniques, microinjection is the most common technology used in the construction of genetically modified animals.[26] Microinjection relates to the transfer of one or two different genes into an animal.[27] With the advance of genetic engineering, scientists are able to isolate and transfer particular genes from the same or different species to create desired genetically modified animals for research and other commercial benefits.[28]

Microinjection technology begins when the DNA constructs composed of a desired gene are separated from the same or different species.[29] These DNA constructs are processed in a laboratory and then inserted into fertilized early stage embryonic cells.[30] Then, the inserted embryos are injected into the female surrogate animals, which carry the genetically modified offspring and then give birth to the genetically modified offspring.[31]

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[23] *Ibid.*, at 120.
[24] Morin, *supra* note 2 at 149.
[25] *Ibid.*
[26] *Ibid.*
[27] *Ibid.*
[28] *Ibid.*
[29] *Ibid.*
[30] *Ibid.*
[31] *Ibid.*

The oncomouse is a genetically modified mouse which is produced with a susceptibility to cancer for cancer research.[32] The oncomouse is created by injecting the cancer susceptible gene into fertilized eggs of mice.[33] Then, the fertilized eggs are implanted into a female surrogate mouse, or "foster mother" and the cancer susceptible gene will develop within the offspring of the foster mouse.[34] The offspring, which is called the "founder," will be tested for the existence of the cancer susceptibility gene, and then mated with regular mice so that 50 percent of the next generation which bears the cancer susceptibility gene according to Mendelian inheritance.[35] Finally, this offspring is suitable for cancer research.[36]

3. Patent law and Biotechnology

Generally, patent law provides protection for an invention which meets the patent criteria which are that the invention be new, useful, and non-obvious. If a biotechnological invention meets the patent criteria, it should be patentable subject matter. Furthermore, s. 2 of the *Patent Act* states that an ""invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[37] Therefore, in order to be patentable subject matter, an invention must fit within the term "art, process, machine, manufacture or composition of matter" or the process thereof. According to s. 42 of the *Patent Act*, a patentee has exclusive rights in "making,

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[32] *Harvard College*, *supra* note 4 at para. 122.
[33] Morin, *supra* note 2 at 149.
[34] *Ibid.*
[35] *Ibid.*
[36] *Harvard College, supra* note 4 at para.122.
[37] ***Patent Act***, R. S. C. 1985, c. P-4, s. 2.

constructing and using the invention and selling it to others to be used...".[38] Since the patentee has exclusive rights conferred by the *Patent Act* to prohibit others from using a patented invention, the *Patent Act* limits the time for holding a patent to 20 years.[39]

3.1 The Patent Criteria

Pursuant to s. 2 of the *Patent Act*, there are three criteria for an invention to be patentable subject matter:

1) New

The invention must be new but it is unnecessary that the invention be so new that nobody has known or thought of making it before.[40] The invention must be relatively new.[41] Moreover, the patent claims for the invention must not have been disclosed anywhere else before the patent application.[42] However, in Canada, there is a one grace period for an inventor to apply for a patent within one year after his or her invention made to public.[43] This one year grace period does not make the invention lack novelty.[44]

2) Non-obvious

The invention must not be obvious at the date of filing the patent application.[45] Non-obviousness is defined as meaning that a person skilled in the art could not copy or imitate the invention easily.[46] Furthermore, the invention should be an improvement from known inventions.[47]

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[38] *Ibid.*, s. 42.
[39] *Ibid.*, s. 29.01.
[40] David Vaver, *Intellectual Property Laws: Copyrights, Patents and Trade-marks* (Toronto: Irwin Law, 1997) at 131.
[41] *Ibid.*
[42] *Ibid.*
[43] *Ibid.*, at 131.
[44] *Ibid.*
[45] *Ibid.*, at 136.

3) Useful

The usefulness of the invention means that "the invention must be operative, controllable and reproducible."[48] Inventions that are inoperative are useless and are not patentable subject matter.[49] Moreover, the usefulness of the invention is determined at the time of the filing of patent application, and "sound prediction" may be taken into account. According to the Manual of Patent Office Practice, "sound prediction" has to be reliable and not depend on "a lucky guess or mere speculation."[50]

To conclude, if inventions including biotechnological inventions meet the three patent criteria, they should be patentable.

3.2 The Relationship between Patent Law and Biotechnology

Biotechnology is not a totally new technology discovered only a few years ago. Rather, biotechnology has been known since Mendel introduced his cross-breeding and hereditary experiments on peas in 1865.[51]

In terms of patent law, whether a genetically modified organism is patentable subject matter or not has been partly clarified. Lower life forms such as yeast, bacteria and fungi are widely accepted to be patentable subject matter in many countries. On the other hand, there is still an argument whether higher life forms should be patentable subject matter. While some countries have granted a patent on higher life forms such as

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[46] *Ibid.*
[47] *Ibid.*
[48] Canadian Intellectual Property Office, "Manual Of Patent Office (MOPOP) online: <http://www.ic.gc.ca/sc_mrksv/cipo/patents/mopop/ch12-e.pdf.>, § 12.01. Last visit: 13 March 2008 [hereinafter cited as "MOPOP"]
[49] Vaver, *supra* note 40 at 138.
[50] MOPOP, *supra* note 48 at §12.05.
[51] National Human Genome Research Institute, "1865: Mendel's Peas" online: National Human Genome Research Institute <http://www.genome.gov/pfv.cfm?pageID=25520230>. Last visit: 13 March 2008.

the oncomouse, other countries such as Canada do not allow patents on genetically modified animals and plants.

The patent law has become involved with biotechnological inventions when the inventions meet patent criteria: novel, useful and non-obvious. The patentability of genetically modified living organisms, particularly genetically modified higher life forms will be discussed further.

3.3 *TRIPS Agreement* and the Patentability of Higher Life Forms

According to Article 27.3 (b) of the *TRIPS Agreement*,

> Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.[52]

Article 27.3 (b) of the *TRIPS Agreement* provides that certain plants and

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[52] World Trade Organization, "Uruguay Round Agreement: TRIPS, Part II - Standards Concerning the Availability, Scope and Use of Intellectual Property Rights," online: World Trade Organization < http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm >. Last visit: 13 November 2007.

animals may be unpatentable subject matter.[53] As a result, higher life forms could be excluded from patentability.[54] The Harvard scientists argued in *Harvard College* that TRIPS provisions allow the grant of patents on plants and animals unless there is a specific provision excluding plants and animals from patentability.[55] However, Bastarache J. opines that Canada should retain the *status quo* that higher life forms are unpatentable subject matter.[56] Bastarache J. also views that TRIPS' provisions merely affirm the distinction between higher life forms and lower life forms.[57] Therefore, the interpretation of the *Patent Act* that higher life forms are not patentable subject matter is not in conflict with *TRIPS Agreement*. When there is no patent protection for genetically modified plants and animals, Canada might need to provide *sui generis* protection for the oncomouse according to Article 27.3 (b) of *TRIPS Agreement*.[58] Moreover, the majority in *Harvard College* preferred issue *sui generis* protection for the oncomouse rather than provide patent protection. On the other hand, the dissent in *Harvard College* disagreed with establishing of *sui generis* protection for the oncomouse. The issue whether there should be a *sui generis* system for the oncomouse will be discussed in Chapter three.

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[53] World Trade Organization, "Pharmaceutical Patents and TRIPS Agreement"," online: World Trade Organization <http://www.wto.org/english/tratop_e/TRIPS_e/pharma_ato186_e.htm.> Last visit: 16 August 2008.

[54] Catherine Geci & Bartha Maria Knoppers, " Patenting of Higher Life Forms: A Canadian Perspective" in Burton Ong, ed., *Intellectual Property and Biological Resources* (Marshall Cavendish Academic, 2004) 163 at 176.

[55] *Harvard College, supra* note 4 at para. 205.

[56] *Ibid.*

[57] *Ibid.*

[58] Burton Ong, "Harnessing the Biological Bounty of Nature: Mapping the Wilderness of Legal, Socio-Cultural, Geo-Political and Environmental Issues" in Burton Ong, ed., *Intellectual Property and Biological Resources* (Marshall Cavendish Academic, 2004) 1 at 8.

4. Cases about the patentability of genetically modified living organism

4.1 *Diamond v. Chakrabarty*

The 1980 case of *Diamond v. Chakrabarty*[59] was the first case in which the U.S. Supreme Court held that living organisms such as genetically modified bacteria were patentable subject matter as "manufactures" or "compositions of matter."[60]

In *Chakrabarty*, Chakrabarty, a microbiologist, applied for a patent for his invention about certain genetically modified bacteria which are useful for degrading crude oil spills.[61] Chakrabarty and his colleagues discovered the capacity of bacteria to break down camphor and octane, which are two components of crude oil.[62] According to the patent application for the invention, Chakrabarty genetically modified four different bacteria into one.[63] There was no problem about the grant of a process patent for Chakrabarty's patent claims. However, there was a problem whether the genetically modified bacteria that Chakrabarty designed could be patentable subject matter. The U.S. Supreme Court held that the genetically modified bacteria are patentable subject matter because the genetically modified bacteria did not occur naturally but due to human manipulation. The U.S. Supreme Court broadly interpreted the term "composition of matter" by relying on Congress' intention that "anything under the sun made by man" is

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[59] *Chakrabarty*, *supra* note 5.
[60] JoAnne Eichellberger Seibold, "Can Chakrabarty survive the "Oncomouse"? (1988-1989) 2 U. Fla. J.L. & Policy 86.
[61] *Chakrabarty*, *supra* note 5.
[62] *Ibid.*
[63] *Ibid.*

patentable subject matter.[64] *Chakrabarty* has become a landmark case of the patentability of biotechnological inventions and other new technology.

4.2 Harvard College v. Commissioner of Patents (Canada)

Harvard scientists filed a patent application in Canada for their inventions in the genetically modified mouse or the oncomouse. The oncomouse is genetically modified in order to be susceptible to cancer for cancer research. The Commissioner of Patents rejected the grant of a patent on the oncomouse because the inventor could not control the development of the oncomouse; as a result, the oncomouse falls outside the word "invention" under s. 2 of the *Patent Act*.[65] The applicants appealed the Commissioner of Patents' decision to the Federal Court, Trial Division, where Nadon J. decided that the oncomouse was not patentable subject matter because the development of the oncomouse cannot be controlled, and the 'laws of nature' were involved in the invention.[66] Furthermore, Nadon J. opined that the applicants claimed a patent for the entire animals not the genetically modified genes or cells; as a result, the patent should not be granted because scientists are not able to reproduce the identical mouse, except for their modified oncogenes.[67] The applicants then appealed the case to the Federal Court of Appeal. The Federal Court of Appeal held that the oncomouse was patentable subject matter as a 'composition of matter.' Rothstein J.A. as he then was writing for the majority in the Federal Court of Appeal opined that the Court could rely on *Chakrabarty*; as a consequence, Rothstein J.A. concluded that the oncomouse could be granted a patent as a

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[64] *Harvard College, supra* note 4 at para.87.
[65] *Ibid.*, at para. 130
[66] *Harvard College v. Commissioner of Patents* [1998] 79 C.P.R. (3d) 98 at para. 24 [hereinafter cited as *Trial Division*].
[67] *Ibid.*, at para 24.

'composition of matter.' Moreover, Rothstein J.A. focused on the usefulness of the oncomouse rather than on control over the entire oncomouse. After the Federal Court of Appeal's decision, the Commissioner of Patents appealed the case to the Supreme Court of Canada. The Supreme Court by a 5-4 majority held that the oncomouse was not patentable subject matter because it is a higher life form. Furthermore, the majority of the Court determined that the Oncomouse was not a "composition of matter" under the *Patent Act*. The issue of "composition of matter" will be discussed in the next chapter.

4.3 Monsanto v. Schmeiser[68]

Percy Schmeiser, a farmer in Saskatchewan, was sued by Monsanto on the basis that Schmeiser had infringed Monsanto's patent in genetically modified canola plants called "Roundup Ready Canola".[69] "Roundup Ready Canola" is a canola plant, which was genetically engineered in order to be glyphosate-herbicide resistant. Glyphosate-herbicide is also a product of Monsanto called "Roundup," used to kill weeds. Farmers entering into agreements with Monsanto have to use "Roundup" to spray on the "Roundup Ready Canola" in order to kill weeds but not the genetically modified canola plants. The legal issue in *Monsanto* was whether Schmeiser infringed Monsanto's patent by planting Roundup Ready canola plants consisting modified genes and cells that are glyphosate-herbicide resistant. Schmeiser argued that he did not infringe Monsanto's exclusive rights on genetically modified canola plants. Schmeiser relied on *Harvard College* arguing that Monsanto did not have exclusive patent rights on "Roundup Ready canola" because canola plants are higher life forms, and therefore, were not patentable

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[68] *Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C. R. 902 [hereinafter cited as *Monsanto*].
[69] *Ibid.*, at para. 4.

subject matter. The Supreme Court in *Monsanto* held that Monsanto had patent rights on modified genes and cells existing within the canola plants. As a result, Schmeiser infringed Monsanto's patent rights by planting canola plants containing modified genes and cells. The majority in *Monsanto* opined that the patentable subject matter in this case is different from that in *Harvard College*. In *Monsanto*, the majority reasoned that the Court has granted a patent protection for the modified genes and cells that make up the canola plants, but not the canola plants themselves. When Schmeiser used the canola plants consisting of the patented genes and cells, Schmeiser infringed patent rights of Monsanto in modified genes and cells because the genes and cells within the canola plants are inseparable from the canola plants.[70]

Another argument made by Schmeiser was that he did not intend to plant genetically modified canola plants consisting patented inventions. The seeds of genetically modified canola plants may have blown from passing trucks or from neighboring areas. The Court concluded that patent infringement did not require intention; therefore, Schmeiser could not argue that he was an innocent bystander. In addition, the innocent bystander defense is not contained within the *Patent Act*.

Conclusion

The examination of the history of the *Canadian Patent Act* and the creation of the oncomouse make us understand the patents on genetically modified animals. However, the interpretations and the Court's opinions on the patentability of the oncomouse are different. As indicated in the cases, the United States granted a patent on the oncomouse,

[70] *Ibid.*, at para. 22.

while Canada did not. According to the different opinions, the next chapter will discuss the Supreme Court of Canada's decision in *Harvard College* and compare with other related cases.

Chapter 2

The *Harvard College* decisions and legal issues

Introduction

This chapter will examine the Supreme Court of Canada's decision in *Harvard College*. The discussion has six parts. First, the interpretation of the term "composition of matter" shall be discussed on the issue of whether the terms include the oncomouse. Second, the "laws of nature" argument will be examined. Third, the 'making' of living and non-living things will be distinguished. Fourth, the 'control' test will be discussed to determine whether it is relevant to the patentability of the oncomouse. The fifth part examines the intention of Parliament from the scheme of the *Act*. Finally, the object of the *Act* shall be determined with respect to whether the grant of a patent on an invention such as the oncomouse will have or have no effects on the patent law.

1. The Interpretation of the words "composition of matter"

In order to be granted a patent, the patent application must meet the patent criteria of being new, useful, and non-obvious, according to s. 2 of the *Patent Act*. Patents provide exclusive rights for patentees to prohibit other people from making, using, selling or importing a patented invention.

To decide whether the oncomouse was an 'invention,' the Court had to define the terms 'composition of matter' and 'manufacture' because if the oncomouse qualified under either of these terms, the mouse will be patentable subject matter.

In terms of 'manufacture,' it is obvious that the oncomouse was not a 'manufacture.' "'Manufacture' connotes a product made manually or by an industrial

process, by changing the character or condition of material."[71] Bastarache J., writing for the majority of *Harvard College*, opined that the Oncomouse could only be a "manufacture" "when it is produced in an industrial setting..."[72]

Therefore, the oncomouse does not fit within the definition of 'manufacture' since the oncomouse is not a mechanical subject matter.

If the oncomouse is patentable subject matter, it must be found to be a "composition of matter."

1.1 "Composition"

According to Bastarache J., writing for the majority, the word "composition of matter" must be interpreted by using the *Oxford Dictionary*. The *Oxford Dictionary* defines the word 'composition' as "[a] substance or preparation formed by combination or mixture of various ingredients."[73] In addition, the *Grand Robert de la langue française* also provides a similar definition.[74] In the creation of the Harvard-oncomouse, the researchers used the recombinant DNA technology to make the mouse susceptible to cancer by injecting the cancer genes into the fertilized eggs.[75]

Bastarache J. accepted that the mouse egg would be mixed or combined by various ingredients by humans, and the genetically modified egg could be classified as "composition."[76]

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[71] Vaver, *supra* note 40 at 123.
[72] *Harvard College, supra* note 4 at para. 159.
[73] *Ibid.*, at para. 162.
[74] *Ibid.*
[75] *Ibid.*
[76] *Ibid.*

> Injecting the oncomouse into a fertilized egg is the but-for cause of a mouse predisposed to cancer, but the process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention. The body of a mouse is composed of various ingredients or substances, but it does not consist of ingredients or substances that have been combined or mixed together by a person. Thus, I am not satisfied that the phrase "composition of matter" includes a higher life form whose genetic code has been altered in this manner.[77]

However, while the oncomouse's egg could have been patentable, according to Bastarache J., the mouse that grows from that egg is not patentable. The oncomouse grows naturally by itself according to 'the laws of nature' without human intervention. [78] Even though the oncomouse body consists of various ingredients or substances, the mixture of the ingredients within the oncomouse does not come from human intervention.[79] Bastarache J. concluded that the genetically modified mouse did not fit within the definition of 'composition.'[80] Therefore, Bastarache J. rejected the patentability of the oncomouse since it was not a composition, but more than a composition.

Compositions of non-living matters have been granted patents under the Canadian patent law. The combination of many kinds of medicines to produce a new and effective medicine could receive a patent.[81] The resulting problem from *Harvard College* is the discrimination between the composition of matter of living things and non-living things.

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[77] *Ibid.*
[78] *Ibid.*
[79] *Ibid.*
[80] *Ibid.*
[81] *Merck & Co. v. Apotex Inc.* (C.A.), 1995 CanLII 3586 (F.C.A). The case discussed the claims over patented composition of matter use in the production of a new medicine.

The Court in *Harvard College* distinguished compositions of matter of living things and non-living things. The difference between living things and non-living things is life forms. When determining the patentability of higher life forms, the court raised the point of 'composition of matter plus something undefined' to make the subject matter unpatentable. If the court interprets the language of the *Patent Act* as it stated, the composition of matter of living things and non-living things should not be different. The composition of matter should be patentable subject matter under the *Patent Act* whether or not it is living things or non-living things, if the creation meets the patent criteria.

1.2. "Matter"

Bastarache J. used the *Oxford Dictionary* to clarify the meaning of the word "matter". According to the *Oxford Dictionary*, 'matter' includes merely "physical or corporeal substance..." not "immaterial or incorporeal substance such as spirit, soul, mind."[82] Bastarache J. held that the definition of 'matter' does not fit with the higher life form such as the genetically modified mouse, although some people believe that higher life forms are matters.[83] For Bastarache J. the oncomouse is not a 'matter' but more than a 'matter.' However, Bastarache J. did not explain what the oncomouse would be, if it was not a "composition of matter."

In addition, Bastarache J. also pointed out that a person will not be changed because his/her genes are modified by radiation.[84]

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[82] *Harvard College, supra* note 4 at para. 163.
[83] *Ibid.*
[84] *Ibid.*

> Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed. A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilized egg cell; it simply would not be predisposed to cancer. The fact that it has this predisposition to cancer that makes it valuable to humans does not mean that the mouse, along with other animal life forms, can be defined solely with reference to the genetic matter of which it is composed.[85]

Similarly, the oncomouse will not turn into another species due to the injection of the cancer gene within fertilized eggs even though the cancer gene will pass on to the next offspring.[86] The economic value of the oncogene consisting within the oncomouse does not make the mouse patentable subject matter.

In contrast, according to Binnie J., the oncomouse is a 'composition of matter' because the mouse was created from the combination of various ingredients and the mouse is also a 'physical substance.'[87] Therefore, if the oncomouse fits the definition of 'composition of matter,' the oncomouse could be patentable subject matter.

> I believe that the extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human modification of "the genetic material of which it is composed" is an inventive "composition of matter" within the meaning of s. 2 of the *Patent Act*.[88]

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[85] *Ibid.*
[86] *Ibid.*
[87] *Ibid.*, at para. 43.
[88] *Ibid.*, at para. 8.

In addition, Binnie J. opined that the word 'composition of matter' should be interpreted broadly to include unanticipated inventions such as the oncomouse.[89] Rothstein J.A., the majority in *Harvard College* in the Federal Court of Appeal, also believed that the Oncomouse fitted the definition of 'composition of matter' since the oncogene is permanently embedded within every cell of the oncomouse and also its offspring.[90] Likewise, the offspring with the oncogene do not exist naturally but they are the consequence of the injection of the oncogene into the founder mouse. If the scientist does not inject the oncogene into the founder mouse, the offspring would not bear the oncogene. As a result, the offspring of the oncomouse are also 'composition of matter.'[91]

With reference to the definition of 'matter' in the *Oxford Dictionary* brought to bear by Bastarche J., Binnie J. argued that if the oncomouse was not 'matter,' what would the mouse be?[92] Binnie J. asserted that the use of a dictionary to find the meaning of the words such as 'matter' within the *Patent Act* was incorrect since it narrows the scope of the *Patent Act* and makes it difficult for future inventions to be patentable.[93]

To support Binnie J.'s argument in the interpretation of 'composition of matter" to include the oncomouse, the majority's opinion in *Chakrabarty* should be considered. In *Chakrabarty*, Burger C. J., for the majority, construed the meaning of 'composition of matter' to include "all compositions of two or more substances and … all composite articles, whether they be the results of chemical union, or of mechanical mixture or

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[89] *Ibid.*
[90] *Harvard College v. Commissioner of Patents (Canada)* [2000] 7 C.P.R. (4th) 41 [hereinafter cited as *Fed. Court Appl.*]
[91] *Ibid.*, at para. 42.
[92] *Ibid.*, at para.45.
[93] *Ibid.*

whether they be gases, fluids, powders or solids."[94] Moreover, Congress intended to include "anything under the sun that is made by man" to be patentable subject matter.[95] When read together, the interpretation of the word 'composition of matter' could include genetically modified animals because of its broad interpretation. However, Binnie J. noted that Burger C. J. did not grant a patent on genetically modified bacteria because the bacteria are "anything under the sun that is made by man."[96] Rather, the patent was granted because the genetically modified bacteria were "manufacture" or "compositions of matter" under the definition provided by Congress.[97] Therefore, in 1988 when the United States granted a patent on the oncomouse, it was considered to be a "composition of matter" in order to be patentable subject matter.

Regarding the arguments brought by the majority and the dissent in *Harvard College* in the interpretation of the word 'composition of matter,' I believe that the arguments brought by the dissent, led by Binnie J., rather than the arguments of the majority, seem to be reasonable and should be applied to the *Patent Act.* The definition of 'composition of matter' should be interpreted broadly to include unforeseeable inventions such as the oncomouse, if such inventions meet the patent criteria. In addition, the CBAC Report in June 2000 recommends that higher life forms such as plants, seeds, and non-human animals, which meet patent criteria, should be patentable subject matter.[98]

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[94] *Chakrabarty*, *supra* note 5.
[95] *Ibid.*
[96] *Harvard College*, *supra* note 4 at para.37.
[97] *Ibid.*
[98] Canadian Biotechnology Advisory Committee, "Patenting of Higher Life Forms and Related Issue: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee," online: <http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwapj/E980_IC_IntelProp_e.pdf/$FILE/E980_IC_IntelProp_e.pdf. > Last visit: 13 March 2008 [hereinafter cited as "The CBAC Report 2002"].

Moreover, the oncomouse has received patent protection in other jurisdictions for many years.

The Bastarache J. opinion that the word 'composition of matter' does not include higher life forms, might eliminate the problems that could occur if patents were granted on humans and human bodies including the animals used in xenotransplantation or the transplantation of human organs into animals in order to use the organ for the replacement of the defecting human organs.[99] However, Bastarache J.'s opinion narrows the scope of the *Patent Act*; and as a result, other new inventions may not receive patent protection. Furthermore, the narrow interpretation of the *Patent Act* will cause the *Patent Act* to become obsolete and require amendment by Parliament.

Are modified genes or cells that exist within the higher life forms patentable subject matter? According to many opinions from the CBAC Report, the European Union, and the United States' concept of the patents on genes and cells, the modified genes and cells of plants and animals are patentable subject matters. To confirm this concept the Supreme Court of Canada in *Monsanto v. Schmeiser* ruled that patent protection was allowed for the modified genes and cells of higher life forms. In *Monsanto*, the court held that modified genes and cells consisting in genetically modified canola plants were patentable subject matter. If a person uses the modified genes and cells, he or she may infringe a patentee's rights. The court in *Monsanto* solved the

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[99] Xenotransplantation includes "any procedure that involves the transplantation, implantation, , or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal sources or (b) human body fluids, cells, tissues, or organs. Furthermore, xenotransplantation products have been defined to include live cells, tissues, or organs used in xenotransplantation." (cited from United States Public Health Service, Department of Health and Human Services, "PHS Guideline on Infectious Disease Issues in Xenotransplantation" (19 January 2001), online: United States Public Health Service< http://www.fda.gov/cber/gdlns/xenophs0101.pdf.>)

problem arising out of *Harvard College* by granting a patent on modified genes and cells of genetically modified plants even though plants as higher life forms are patentable subject matter under the *Canadian Patent Act*.

Difficulty still exists in the protection of the patentees' rights because higher life forms themselves are not protected under the *Patent Act*. I believe that it is unreasonable to limit the scope of 'composition of matter' merely to non-living things and lower life forms because it fits the definitions in dictionaries, whereas the higher life forms are not patentable subject matter since they do not fit the definition provided in the dictionary. The dissent's opinion seems to be widely accepted rather than the majority's opinion because the dissent tends to be consistent with the landmark case about the patentability of the biotechnological invention in *Chakrabarty*. Furthermore, the latest case about the patentability of genetically modified higher life forms such as *Monsanto* still tries to find a solution to provide protection for higher life forms.

Another moral issue at work from the majority decision in *Harvard College* is that the patentability of the oncomouse may lead to the patentability of humans.[100] The majority in *Harvard College* is concerned that humans could be patentable subjects if there is a grant of a patent on the oncomouse because the mouse cell lines are close to human cell lines. However, when modified genes and cells of higher life forms are patentable subject matter according to *Monsanto* decision, would the case be applied to modified genes and cells of human? If there is no regulation to prohibit humans from patentability, modified genes and cells of humans would be patentable subject matter and

[100] Morin, *supra* note 2 at 171.

it would lead to patents on humans. For this issue, I want to use the dissent's argument in *Harvard College* that humans are unpatentable subject matter under ss. 7 and 15 of the *Canadian Charter of Rights and Freedoms*.[101] Therefore, the denial of the patentability of the oncomouse does not solve the problem of patenting on humans unless there is a specific regulation. If there is no regulation to prohibit humans from patentability, modified genes and cells of humans would be patentable subject matter and it would lead to patents on humans.

2. The "Laws of Nature"

Binnie J. argued that the "laws of nature" should not be a factor to determine whether an invention is patentable subject matter since the "laws of nature" are involved in every invention.[102] Binnie J. also gave the example of AZT, a drug used to treat HIV patients. AZT was patented although there was some "laws of nature" involved in the production of the AZT.[103] Similarly, the genetically modified mouse should not be considered un-patentable just because the oncomouse grows naturally following the "laws of nature" even though the oncomouse is new, non-obvious, and useful.

Rothstein J.A. in the Federal Court of Appeal in *Harvard College* opined that even though the 'laws of nature' are involved in the growth of the oncomouse, the natural process of growing does not stop the oncomouse from being a 'composition of matter.' Rothstein J.A. also believes that the oncomouse is the consequence of both human manipulation and the 'laws of nature.'[104] If there is no human intervention, the

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[101] *Harvard College, supra note* 4 at para. 54.
[102] *Harvard College, supra* note 4 at para.87.
[103] *Ibid.*
[104] *Fed. Court.Appl., supra* note 90 at para. 52.

oncomouse would not exist because the 'laws of nature' alone cannot create the oncomouse. Inventions relying merely on the 'laws of nature' would exclude the inventions from patentability.[105] Involvement of the 'laws of nature' in biological inventions such as the oncomouse does not exclude the inventions from patentability, according to Binnie J.[106] Therefore, the oncomouse could be patentable subject matter, even though there is the 'laws of nature' involved in the creation of the oncomouse.[107] In addition, in *Monsanto*, McLachlin C. J. and Fish J., writing for the majority, asserted that 'natural processes' have operated in many inventions.[108]

On the issue of 'the laws of nature,' the dissent is right about the operation of the 'laws of nature' in that even though "the laws of nature" are involved in the creation of an invention, "the laws of nature" do not bar patentability. However, to examine whether the "laws of nature" answer the point the majority made, the difference between the operation of "the laws of nature" in living organisms and non-living things should be taken into account. The majority made the point that the oncomouse grows naturally even though the oncogene is injected into the founder mouse and the oncogene is passed on to the next offspring. The mouse does not change into another species except their modified genes and cells which are passed to its offspring. The majority does not believe that the genetically modified mouse fits within the term 'composition of matter' since the growth of the mouse is following the 'laws of nature.' However, I believe the actual reason the majority did not grant a patent on the oncomouse was because the genetically modified

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[105] *Ibid.*
[106] *Ibid.*
[107] *Ibid.*, at para.53.
[108] *Monsanto, supra* note 68 at para. 91.

mouse is a higher life form, and it might lead to the patentability of humans eventually. The examples provided by the dissent about the 'laws of nature' could answer whether higher life forms, which are natural things and grow naturally, whether they are plants or animals, are patentable subject matter.

The 'laws of nature' which involve patented inventions such as AZT drugs should be compared with the operation of "the laws of nature" in living organism whether or not "the laws of nature" work differently in living and non-living things. If "the laws of nature" do not work differently the patentability of non-living things involving "the laws of nature" should be applied to the patent on living organisms when the living organisms meet the patent criteria despite the difference in the subject matter itself. In other words, the 'laws of nature' should not be a factor to eliminate the living things from patentability. If the 'laws of nature' work differently for living things and non-living things, the patentability of the living things should be considered.

The production and reproduction of non-living things face much less public opposition than the production and reproduction of living organisms. As noted previously, in some cases, the production and reproduction of living things such as humans or parts of human bodies are considered immoral. I shall conclude that the operation of 'the laws of nature' in living and non-living things works the same. However the subject matter in which 'the laws of nature' operates is different.

The exclusive rights of patentees provide opportunities for commercial gain.[109] As a result, there is more concern over patents on living things such as genetically

[109] Vaver, *supra* note 40 at 151.

modified animals than on non-living things. When commercial gain involves living things, particularly higher life forms, it is a dilemma to decide whether or not to provide patent protection for the higher life forms. Even in the Harvard College scientists' patent claims for the oncomouse, they claimed that they invented modified genes and cells, not that they invented a life.[110]

Rothstein J.A., in The Federal Court of Appeal in *Harvard College* commented on the issue of the 'laws of nature' that the oncomouse is the combination of ingenuity and the 'laws of nature,' and both are equally important. Therefore, ingenuity also plays a significant part in the creation of the oncomouse not merely the 'laws of nature.' The oncomouse should not be excluded from patentability because the 'laws of nature' are involved in the creation of the oncomouse. In summary, if higher life forms are determined to be patentable subject matter, the 'laws of nature' which operate in the creation of the higher life forms should not be used to exclude the higher life forms from patentability.

3. "Making" Living Things and "Making" Non-Living Things

The consideration of the operation of the 'laws of nature' in living things and non-living things leads to the determination of the patentees' rights under the patent law. The word 'make' is important. The patent is a set of exclusive rights conferred to the patentees by the patent law. A patentee has the right to 'make' the invention. The question is the whether 'making' in living things is different from 'making' in non-living things. For non-living things, the word 'manufacture' can be applied. This term cannot be

[110] *Harvard College, supra* note 4 at para. 69.

used for living things because the term 'manufacture' is applied to mechanisms. However, the word 'make' can sometimes be applied to both living and non-living things as in 'make' a mouse and 'make' a toaster.

In the case of "making" living things, the production and reproduction by human manipulation can control only the modified genes and cells, but not the appearance or characteristics of the living things. The exception is the use of cloning technology. On the other hand, the "making" of non-living things can be controlled because the inventions do not involve life. The study of the construction of non-living things is much less complicated and can be solved. However scientists still cannot study the entire structure and composition of living organisms such as DNA. As a consequence, the control of every aspect of living organisms is difficult. Making of living things and making of non-living things should be compared in the way that the invention can be made or reproduced. Making of living things such as the oncomouse should use modified genes and cells to compare with making of non-living things because modified genes and cells are made or reproduced not the appearance of the oncomouse.

4. The 'Control' Test

According to Barrigar, 'control' may be an important factor to consider when determining whether or not an invention is 'useful,' even though the invention involves 'the laws of nature.'[111] The Manual of Patent Office Practice makes the same comment.[112] Furthermore, the Manual of Patent Office Practice states that "the invention

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[111] Robert Barrigar, *Canadian Patent Act Annotated*, (Aurora, Ont.: Canada Law Book, 1994) at PA-28.15.
[112] MOPOP, *supra* note 48 at §12.02.

must be operative, controllable and reproducible" in order to meet the "utility" criterion of the patent criteria.[113]

However, in *Harvard College*, the Supreme Court did not determine the issue of 'control' over the oncomouse in the patentability of the oncomouse.[114] Rather, the Court considered the case on the determination of "manufacture" or composition of matter."[115]

The issue of the 'control' over living organisms was discussed in the Trial division and Federal Court of Appeal. Nadon J. in the Trial Division in *Harvard College* refused the grant of a patent over the oncomouse because the oncomouse cannot be controlled under the patent requirements. Nadon J. held that the inventor had to predict "the location, presence, and quality of the gene" in order to prove the reproducibility of the invention.[116] The oncomouse cannot be reproduced completely because the consequence or the mouse itself is not reliable and depends on "luck and chance," according to Nadon J.'s opinion.[117] Nadon J. also stated that the 'laws of nature' and human intervention were inseparable, even though the modified genes are new but the mouse is not new.[118]

On the other hand, the Federal Court of Appeal determined that the control test is used with process claims not product claims in the case of patent application for living organisms.[119] The Court of Appeal further stated that the importance of the determination

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[113] *Ibid.*
[114] Barrigar, *supra* note 111 at PA-28.15.
[115] *Ibid.*
[116] Matthias Kamber, "Coming Out of the Maze: Canada Grants the Oncomouse Patent" (2003) 35 George Washington International L.R. at 768.
[117] *Ibid.*
[118] *Trail Division, supra* note 66 at para. 22.
[119] Kamber, *supra* note 116 at 770.

of the usefulness of the invention is the control over the modified genes of the oncomouse and the 'control' of the characteristics of the mouse are not relevant.[120] Rothstein J.A. also stated that the 'control' test applied by the Commissioner of Patents and the Trial Judge was too broad to include every aspect of the oncomouse such as the length of the tails, the colour of the eyes, and the textures of the mouse's fur.[121]

Rothstein J.A. held that if the oncomouse could be reproduced with the offspring carrying the oncogene, the oncomouse is in fact reproduced and therefore useful.[122]

The control test applied to living organisms and non-living organisms is that the inventor must control the important characteristics of the invention. It is unnecessary to control every aspect of the invention. Particularly in living organisms, it is impossible to control completely the exact characteristics of the living organisms. However the modified genes and cells of the living organisms can be completely controlled. For example, with the oncomouse, only modified oncogene can be controlled, not its tail length or eye colour.

When applicants apply for a patent, they do not apply for a patent on the living organisms but for the mouse consisting of modified gene and cells. The living organisms can be reproduced with the offspring carrying the modified genes and cells such as the oncomouse.

In the case of the 'control' over non-living things, there is less complication. The inventor is able to predict, control and reproduce every aspect of every characteristic of non-living things.

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[120] *Fed. Court Appl., supra* note 90 at para. 74.
[121] *Ibid.*
[122] *Ibid.*, at para. 84.

I would like to conclude that living things and non-living things can be controlled and reproduced in order to be patentable. This is a fact even though there are some differences in the control test and reproducibility according to the different characteristics of subject matter for living things and non-living things.

According to the majority's opinion, in *Harvard College*, in the interpretation of the word 'matter,' Bastarache J. views that the oncomouse is more than 'matter' due to its complex characteristics. Bastarache J. concluded that it is difficult to conceptualize the oncomouse to be merely a 'matter.' It is easier to conceptualize a subject matter such as chairs, tables, and computers to be matter because they can be controlled, whereas the living things such as animals and plants cannot be controlled.

Despite the fact that the oncomouse meets the patent criteria the following question can be asked. If the oncomouse was not a 'composition of matter,' what would the mouse be? And what if the mouse is not a 'composition of matter,' but more than a 'matter,' what kind of intellectual protection is applied in order to protect the oncomouse from free-riders who would circumvent the invention without paying the creators or respecting the inventor's rights? This problem requires Parliament to either amend the current *Patent Act* or issue a *sui generis* system to protect inventions such as the oncomouse. Which mechanism is an appropriate solution? It is Parliament's duty to weigh the advantages and disadvantages of the amendment of the *Patent Act* or the issuing of the *sui generis* system. This would provide higher life form protection similar to the plant variety protection afforded in the *Plant Breeders' Rights Act.*

5. The Scheme of the *Act*

The scheme of an Act is an indication of the purpose of the Act.[123] The courts interpret the purpose of the Act by analyzing the whole Act and all topics included within the Act. The *Patent Act* does not expressly state whether or not an invention such as the oncomouse is patentable subject matter. Therefore, in *Harvard College* the Supreme Court examined the scheme of the Act in order to determine whether or not Parliament intends to allow a patent on higher life forms. Nevertheless, the majority and the dissent in *Harvard College* disagreed in their assessment of the scheme of the *Patent Act*.

5.1 The majority opinion in *Harvard College*

In *Harvard College*, the majority in a judgment by Bastarache J. held that the oncomouse was not patentable subject matter under the *Patent Act* because (in part) of the lack of regulatory framework within or outside the *Patent Act*. The regulatory framework is a specific regulation to control the use of the invention and to protect the public's interest while balancing the patentees' exclusive rights. Bastarache J. stated that the lack of regulatory framework is an indication from the scheme of the Act that Parliament does not recognize the oncomouse and the like inventions to be patentable subject matter. Bastarache J. concluded that the *Patent Act* was 'ill-equipped' to deal with the patenting of higher life forms, and that Parliament did not intend to extend the definition of 'invention' to higher life forms.[124]

The consideration of the scheme of the *Patent Act* by the majority in *Harvard College* raises two points to be examined as follows:

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[123] Ruth Sullivan and Driedger, *Construction of Statutes*, 4th ed. (Canada: Butterworths, 2002) at 215.
[124] *Harvard College, supra* note 4 at para. 167.

(a) The lack of regulatory framework means that Parliament did not intend to include higher life forms to be patentable subject matter

Bastarache J. pointed out that biologically based inventions such as higher life forms have different characteristics from other inventions in that they are living and self-replicating.[125] Due to the self-replicating characteristics of higher life forms, a patent includes not only the higher life forms but also their offspring carrying modified genes and cells.[126] Bastarache J. quoted the CBAC as stating that the grant of a patent on higher life forms would provide the patentees with more rights than other patentees in other fields.[127] Due to the unique characteristics of higher life forms, there should be a regulatory framework for the higher life forms. If there is no regulatory framework, the Court in *Harvard College* considered that there was no intention from Parliament and from the scheme of the Act to include higher life forms to be patentable subject matter. Bastarache J. affirmed in *Harvard College* that the *Patent Act* cannot solve the problem whether higher life forms are patentable subject matter. Batarache J. also stated that if Parliament intends to include higher life forms to be patentable subject matter, Parliament would acknowledge this in the *Patent Act* because the genetic engineering was a known technology at the time of the passage of the *Patent Act*.

(b) The Court does not have a duty to interpret the Act broader than Parliament's intention

Bastarache J. opined that the Court could not grant a patent on the oncomouse because there is no clear indication of Parliament's intention to permit this. The Court is

[125] *Ibid.*, at para.170.
[126] *Ibid.*
[127] *Ibid.*.

not a proper institution to decide on this issue.[128] If there is no clear intention from Parliament, the Court will not grant a patent on an invention broader than Parliament's intention.

To support the majority's opinion in *Harvard College*, the dissent in *Chakrabarty* led by Brennan J., argued that whether living organisms should be patentable subject matter should be left to Congress, not the Court.[129] Brennnan J. seems to believe that in the absent of Congress' intention, the patent on living organisms should not be granted. Brennan J. also stated that the patent law has made an effort to balance the public's interest with the need to encourage technological progress.[130] Due to the delicate issue of the balance of the public interest and the patent law, Brennan J. expressed that the Court should not provide patent protection more expansively than the Congress does, particularly where there is a lack of manifest legislative intention.[131]

5.2 The dissenting opinion

Binnie J. argued that the lack of regulatory framework in the *Patent Act* did not cause the higher life forms to be unpatentable subject matter.[132] Moreover, the absence of a regulatory framework whether in or outside the *Patent Act* is not evidence that the courts are mandated to deny patents on the grounds that there are social, economic, and

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[128] *Ibid.*, at para. 183.
[129] *Chakrabarty*, *supra* note 5.
[130] *Ibid.*
[131] *Ibid.*
[132] *Harvard College*, *supra* note 4 at para. 79.

cultural impacts from the inventions.[133] Furthermore, Binnie J. suggested that the regulatory framework should not be contained in the *Patent Act*.[134]

The dissent's opinion in *Harvard College* raises three important points to be considered as follows:

(a) The lack of regulatory framework does not exclude higher life forms from patentability

According to Binnie J.'s opinion, Parliament has demonstrated a preference for issuing the regulatory framework outside the *Patent Act* rather than within the *Patent Act*.[135] However, Binnie J. argued that the existence or non-existence of regulatory framework has no impact on the interpretation of the term 'invention.'[136] Binnie J. also provided certain examples to illustrate that the lack of specific regulatory framework does not bar unexpected inventions from patentability. For example, nuclear technology was granted a patent in 1869 before the discovery of the theory of atomic disintegration by Ernest Rutherford and Frederick Soddy.[137] Another example is that many kinds of medicines were granted patents without the specific regulations from the legislature when the inventions were patented.[138] These examples demonstrate that if the invention meets the patent criteria, it can be patentable subject matter. It is unnecessary for regulatory framework for the invention to exist at the time of the grant of a patent on an invention. Binnie J. also pointed out that regulatory framework should follow the inventions not

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[133] *Ibid.*, at para. 81.
[134] *Ibid.*, at para. 83.
[135] *Ibid.*
[136] *Ibid.*
[137] *Ibid.*, at para 82.
[138] *Ibid.*

precede them.[139] Thus, even though there is no specific regulatory framework within or outside the *Patent Act*, an invention should be granted a patent. Likewise, the invention like the oncomouse should not be excluded from patentability because of the lack of regulatory framework, according to Binnie J.

(b) The Court has a duty to interpret the words of the Act to include unexpected inventions

On the issue of the Court's duty, the Court has a duty to grant a patent on an invention if there is a clear intention by Parliament on the particular type of the invention. The problem in *Harvard College* is that the words of the *Patent Act* are unclear on whether they include the oncomouse as patentable subject matter. The majority's opinion might seem restrained rather than activist on the legal issue. The *Harvard College* majority and *Chakrabarty* majority, view the court's duty and legislature's duty in the interpretation of the words of the *Patent Act* differently. The majority in *Chakrabarty* and the dissent's opinion in *Harvard College* merely agreed that the legislature is the most appropriate institution to provide the words of the *Patent Act* not the Court. But if legislative language is unclear, the majority in *Chakrabarty* opined that it is Congress' duty to define the words of the Act, while it is the court's duty to interpret the legislature's intention.[140] The *Harvard College* majority, on the other hand, took the view that because Parliament did not contain the patentability of higher life forms within the *Patent Act*, Parliament did not intend to include higher life forms to be patentable subject matter, and it is not the court's duty to interpret the words of the Act broader than the

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[139] *Ibid.*
[140] *Chakrabarty*, *supra* note 5.

Parliament's intention. Therefore, the majority in *Harvard College* concluded that the current *Patent Act* is 'ill-equipped.'

In my opinion, it is also true that Parliament has a duty to establish the words in the *Patent Act*; however, it should be the Court's duty to construe the meaning of the words because the Court is a proper institution in the application of laws and the reason can be seen from the dissent's opinion in *Harvard College* and *Chakrabarty*. When the court denies construing the meaning of the words of the Act, Parliament will rely on the court's interpretation because the courts' decisions restrain Parliament's intention. The courts should not refuse to interpret the words of the Act since it is the court's duty. If the courts refused to do their duty, the result will be problematic in the interpretation of the words of the Act as occurring in *Harvard College*.

(c) The prohibition of patenting on humans is an example of a regulatory framework outside the *Patent Act*

Another concern arising out of *Harvard College* is that, according to Bastarache J., for the majority, the grant of patents on higher life forms such as the genetically modified mouse might lead to the patenting of humans or human parts.[141] Bastarache J. believes that if the *Patent Act* cannot provide the clear language concerning the patenting higher life forms to exclude humans or human parts from patentability, the grant of a patent on higher life forms should not be allowed.[142]

Responding to the concern over the patenting of humans or human parts, noted by Bastarache J., Binnie J. argued that the law prohibited patents on humans, since it is

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[141] *Harvard College, supra* note 4 at para.179.
[142] *Harvard College, supra* note 4 at para. 179.

common ground that humans cannot be owned and exploited.[143] The foundation for the prohibition of the exploitation of humans is contained within ss. 7 and 15 of the *Canadian Charter of Rights and Freedoms*.[144] Therefore, the slippery slope to patents on humans or human parts was not a concern, according to Binnie J's opinion because humans and human parts cannot be exploited and patented according to ss.7 and 15 of the *Canadian Charter of Rights and Freedoms*.

Remarkably, the *Canadian Charter of Rights and Freedoms* is an example of a regulatory framework outside the *Patent Act* in the issue of the prohibition of the patenting on humans and human parts. If the oncomouse is granted a patent, regulatory framework may be established in or outside the *Patent Act* such as the *Canadian Charter of Rights and Freedoms*.

5.3 The analysis of the scheme of the Act

Given the majority's and the dissent's opinion on the scheme of the Act, I shall provide my opinion on whether the scheme of the Act supports the patentability of higher life forms. There are two issues to be considered as follows:

(a) The lack of regulatory framework

In my opinion, the *Patent Act* is not completely 'ill-equipped' to deal with the patentability of higher life forms. I agree with Binnie J.'s opinion that the lack of regulatory framework to deal with new inventions should not exclude the inventions from patentability, and the lack of regulatory framework should not lead to the conclusion that the scheme of the Act excludes higher life forms from patentability. If the words of the

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[143] *Ibid.*, at para.54.
[144] *Ibid.*

Patent Act are interpreted broadly to include the patentability of unanticipated inventions, the *Patent Act* will be useful to include the patentability of the unexpected invention whether or not a regulatory framework exists within or outside the *Patent Act*.

The consequences of the patented invention are sometimes unknown. It may have a negative or positive impact on the people and environment. When the invention is granted a patent, there has been no extensive use of the invention by the patentees and other people except the conducting research and experiment on the inventions by the patentees because the invention needs to be new. As a result, it is highly likely that the legislature or even the inventors themselves cannot predict the exact consequence of the inventions. If the invention has been used by patentees and other scientists, the regulatory framework that issue after the inventions will be more reliable and applicable because the patentees and others will know the consequence of the inventions from the use of the invention. The purpose of the patent is to promote advance and scientific technology.

Therefore, the grant of a patent does not mean that the inventions are safe or dangerous to people and environment. Therefore, the regulatory framework becomes involved in the controlling the use of the patented inventions not dictating whether or not the inventions should be patented.

I agree with Binnie J.'s opinion that the absence of an applicable regulatory framework should not bar higher life forms from patentability. While a regulatory framework provides regulations for public safety, it should not affect the *Patent Act*. Without a regulatory framework, there may be reluctance to grant patents over higher life forms because the patentee's rights may be too broad. In order to protect the public

interest, a regulatory framework is desirable. Even though the specific regulatory framework for the inventions like the oncomouse may be established later, this does not mean that the patent on higher life forms should not be recognized now.

The oncomouse is not different from other inventions which are patentable subject matter except it is a higher life form, and the mouse meets the patent criteria. The difference between the oncomouse and other new technological inventions is that the oncomouse is a living thing, whereas others are non-living things or machinery or lower life forms. However, whether or not the oncomouse is a living thing cannot be used to determine the patentability of the oncomouse because lower life forms such as bacteria, fungi, which are also living things, are patentable subject matter. Consequently, the CBAC 's recommendations might be solution for this problem. If the oncomouse is patentable subject matter, there should be regulatory framework in order to deal with patenting on higher life forms. The issue of the recommended regulatory framework if there is a grant of a patent on the oncomouse will be discussed in chapter four.

(b) The Court's duty in the interpretation the words of the Act

The words of the *Patent Act* are broad enough to include creations like the oncomouse. The majority of the Supreme Court tried to find ways of limiting the meaning of the words, so that they could not include the oncomouse. Because Parliament did not provide a clear enough indication that the Act would apply to the oncomouse, the majority was prepared to conclude that it did not apply.

The majority's approach might seem to show interpretative restraint. The majority was not seeking to push legal protection beyond statutory boundaries. That is, the majority's approach might seem to be respectful of Parliament and the Act.

However, the majority's approach may be argued to be disrespectful of Parliament and the Act, and intrusive on the legislative process.

The majority's narrow reading makes Parliament do what the majority requires. The majority, in effect, considers the plain application of the Act to be too broad. The majority, in effect, substitutes its view for what should be patentable for Parliament.

The grant of patent on the oncomouse is a public policy issue. Therefore, the most appropriate institution to grant a patent on the oncomouse should be considered between Parliament, which is the people's representative and the use of judicial power through the court. According to the CBAC, Parliament is the most appropriate institution to determine the patentability of genetically modified plants and animals.[145] Practically, the Court really forces Parliament to make legislative change by formulating what should be and should not be patentable subject matter.[146]

However, the Court in *Harvard College* refused to do this assigned job. The Court should not get into all sorts of policy issues and issues about consequences because that is Parliament's duty to figure out what to do. The Court can identify problems, but the Court cannot refuse to do its job. When the Court did not do its job on the interpretation of the words of the *Patent Act*, the result in *Harvard College* is that oncomouse was unpatentable subject matter. Furthermore, there may not be legislative change in the

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[145] The CBAC Report 2002, *supra* note 98 at 7.
[146] *Ibid.*

future because the Court denied opining whether or not the oncomouse was patentable subject matter. If the Court in *Harvard College* did its job by interpreting the words of the Act, there would not be a problem about the grant of a patent on higher life forms.

6. The object of the Act

In *Harvard College*, the majority mentioned the importance of understanding the object of the *Patent Act*.[147] Construing of the object of the Act will assist the Court to determine whether the grant of a patent of the oncomouse follows the object of the Act or not. However, the Court upheld that the oncomouse was unpatentable subject matter thereunder.

6.1 The Majority Opinion on the Object of the Act

Bastarache J. accepted that the object of the *Patent Act* is "to advance research and development and to encourage broader economic activity."[148] The oncomouse would seem to advance research and development of biotechnology. Moreover, the grant of a patent on the oncomouse will lead to the grant of patents on other new and unanticipated inventions. Nevertheless, Bastarache J. did not accept that "anything under the sun that is made by man" according to *Chakrabarty* was patentable subject matter since Parliament intends to define 'invention' exhaustively not expansively. Even though the object of the *Act* is very important for construing the *Patent Act*, Bastarache J. held that the object of the *Act* did not dictate the interpretation of the *Act* in determining whether or not a particular invention is patentable subject matter.[149]

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[147] *Harvard College, supra* note 4 at para. 184.
[148] *Ibid.*, at para.185.
[149] *Ibid.*

Bastarache J. opined that the object of the *Act* had to be understood contextually not because of the pressure from the advance of technology and economic benefits.[150]

6.2 The dissent's opinion on the Object of the Act

According to the dissent, not recognizing a patent for the oncomouse means that the *Patent Act* fails to do two things.

(a) The *Patent Act* does not promote flow of scientific information to society

According to Binnie J., a patent provides exclusive rights for a patentee, while "the grant of a patent simply reflects the public interest in promoting the disclosure of advancements in learning by rewarding human ingenuity."[151] Binnie J. also stated that the advance of technology and innovations are the 'lifeblood' of a modern economy because patents provide exclusive rights for a limited time for patentees to prohibit others from exploiting advantages from the invention without the patentees' permission.[152] Without the patent protection, there will not be a free flow of scientific information to society because scientists will fear that they will not receive patent protection for their inventions.

(b) The *Patent Act* does not promote technological advancement

Binnie J. opined that the context and scheme of the *Patent Act* required that word "composition of matter" be interpreted in a broad sense to include an invention such as the oncomouse.[153] Binnie J. stated that the purpose of the grant of a patent, according to the Parliament's intention, was to encourage 'new and useful inventions,' even though at

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[150] *Ibid.*.
[151] *Ibid.*, at para. 4.
[152] *Ibid.*
[153] *Ibid.*, at para. 11.

the time of the grant of the patent the patentee might not know the effect of the invention.[154] The rejection of the patent on the oncomouse may bar technological development. The interpretation of the object of the Act in a narrow way may cause other kinds of technological advance to be unpatentable.

6.3 The analysis of the object of the Act

The object of the Act is the promotion of technology and development. On the one hand, the majority opined that the rejection of the patentability of the oncomouse would not be against the object of the Act because the *Patent Act* does not include the oncomouse to be patentable subject matter. On the other hand, the dissent argued that the rejection of the grant of a patent on the oncomouse would not promote technology and development because other technologies will be obstructed from patentability due to *Harvard College* decision.

There are two significant points to be raised to analyze the object of the Act subsequent to the majority's and the dissent's opinions as follows:

(a) The promotion of technology and development

If the *Patent Act* is interpreted narrowly, the *Patent Act* will become obsolete and not useful in attaining as its original purpose. Inventions developed more rapidly rather than the law; therefore, it is difficult to amend the law every time new and unanticipated inventions occur. The solution is to interpret and apply the *Patent Act* broadly in order to deal with many new inventions. I believe that the term 'invention' should be open-ended in its interpretation in order to promote technological development and the economy in

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[154] *Ibid.*

accordance with the object of the *Patent Act*. The *Patent Act* was enacted in order to encourage scientists and others to create new inventions and technologies.

(b) The free flow of the scientific information among scientists

In *Harvard College*, the Court did not grant a patent on the oncomouse even though the oncomouse is a new invention and meets the patent criteria. The Court's decision, therefore, may lead to a fear among scientists that they will not receive patent protection for their inventions. The result might be that scientists will keep their inventions secret rather than disclose such inventions to the public. Moreover, scientists may find patent protection in countries other than Canada. On the contrary, an advantage of the denial of the patent on the oncomouse is that scientists are able to use the invention without the fear of the patent infringement, and the result may be the exchange of scientific information among scientists. In this approach, patent may become the bar to access to technology when the grant of patents is too broad.[155]

In Canada, the *Patent Act* should be applied as a tool to advance new technologies rather than shutting the door to innovations in the case of the biotechnoligal inventions such as the oncomouse. According to Dan L. Burk's approach, the *Patent Act* should be interpreted broadly in order to promote advance technology and innovations according to the object of the *Patent Act*. This approach tends similar to the dissent's opinion in *Harvard College*. However, the grant of patents on advance technology should not be so broad that patents become a bar to access to technology.

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[155] "Patent Battle over teaching tools: Internet law professor Michael Geist says a patent row between educators and the maker of the educational software tools holds a lesson for all net users." *BBC News* (14 August 2006) online: BBC News <http://news.bbc.co.uk/1/hi/technology/4790485.stm. >

Conclusion

According to the majority's opinion in *Harvard College*, the oncomouse was not a "composition of matter" and there were "laws of nature" greatly involved in the creation of the oncomouse including in other legal issues such as the 'making' of the living and non-living things and the 'control' test. Therefore, the oncomouse was not patentable subject matter. However, the dissent disagreed. The consequence is that there are no laws and regulations to intellectually protect the inventor of the oncomouse and the oncomouse itself. This consequence leads to the third chapter about the consideration the *sui generis* system such as the *Plant Breeders' Rights Act* should be applied to the invention such as the oncomouse.

Chapter 3

The Plant Breeders' Rights Act

Introduction

A *sui generis* system is a specific regulation system designed to protect certain inventions which do not fit within any other kinds of laws and regulations. The *Plant Breeders' Rights Act (PBRA)* is a *sui generis* system established to protect plants produced from plant breeding and plant breeders' rights. According to Article 27. 3 (b) of *TRIPS Agreement*, a member may provide patent protection or a *sui generis* system for plants or animals. The Supreme Court of Canada in *Harvard College* held that the oncomouse was unpatentable subject matter. Canada might need to decide whether there should be a *sui generis* protection for the oncomouse. This chapter shall determine whether regulation like the *PBRA* is suitable for the oncomouse. In this chapter, there are two parts to be considered. First, the general concept of the *PBRA* and the breeding plants and animals are examined and *Pioneer Hi-Bred v. Canada*, which is a case involved with the breeding plant. The second part is the consideration of the application of the *PBRA* to *Harvard College v. Canada*. Moreover, this part will involve the consideration of the majority and the dissent opinions about the *PBRA*.

1. The *Plant Breeders Rights Act* and Breeding Plants and Animals

The genetic modification of plants and animals has been practiced by breeders for more than a thousand years. There are two important technologies used by breeders. The first one is the cross-breeding method. This involves the cross-breeding of two species of

plants and animals to produce a new species.[156] The result from the cross-breeding method is a hybrid animal or a hybrid plant, which provides better characteristics than the parents.[157] The disadvantage of the cross breeding method in animals is that valuable genes contained in the crossbred animals will not be passed on to their offspring, and some species of animals are sterilized such as mules.[158] The second method is selective breeding. The breeders select for breeding the best physical or psychological characteristics of animals and plants in the same species in order to produce plants and animals with the desired characteristics.[159]

The animals bred from both methods are not patentable subject matter because of the lack of satisfaction of the new and non-obvious patent criteria.[160] Animals that have been developed from traditional breeding consist of more than one already known animal breed.[161] Also, the cross-bred animals lack non-obviousness criteria because breeders use available known traditional technology.[162]

For breeding plants, there is not much difference in the breeding methods; however, plant varieties are a little more complicated than those of animals. As a result, the plant varieties and cross-bred animals are categorized as the same rank.[163]

The breeding animals cannot be said to possess unique characteristics due to the combination of a large amount of genes of various breeds.[164] If an animal breed can be

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[156] Nicolas Peace & Andrew Christie, "Intellectual Property Protection for the Products of Animal Breeding" (1996) 4 European Intellectual Property Review 214.
[157] *Ibid.*
[158] *Ibid.*
[159] *Ibid.*, at 215.
[160] *Ibid.*, at 220.
[161] *Ibid.*
[162] *Ibid.*, at 221.
[163] *Ibid.*, at 151.

distinguished from others because of its specific genes, the animal may be patentable subject matter since it is new.[165] However breeding plants and plant varieties are not patentable subject matter because plants are difficult to describe in the written description for the application of a patent. There is, however, provision for the intellectual protection for plant varieties in international agreements such as the *Protection of New Varieties of Plants 1961 ('UPOV Convention').*[166]

In Canada, animals as such are not patentable subject matter. Likewise, the breeding plants and plant varieties are not protected under the *Patent Act*. Nevertheless, breeding plants and plant varieties receive intellectual protection under the *Plant Breeders Rights Act*. The issue of the patentability of animals was sparked in *Harvard College*, after the Supreme Court held that the genetically modified mouse was not patentable subject matter. Moreover, there is a suggested solution from the majority to enact specific legislation to protect inventions like the oncomouse.

1.1 *The Plant Breeders Rights Act*

The *Plant Breeders' Rights Act* (*"PBRA")* could be a model of intellectual property protection for the oncomouse in the same way as it is for the protection of cross-bred plants and plant varieties. The *PBRA* was enacted in 1990 after the Supreme Court's decision in *Pioneer Hi-Bred*. The purpose of the *PBRA* is to provide intellectual protection for new plant varieties, which are not protected under the *Patent Act* because the plant varieties do not technically meet the patent criteria, but which need some kind

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[164] *Ibid.*, at 221.
[165] *Ibid.*
[166] *Ibid.*, at 151.

of intellectual protection.[167] In 1990, the issue whether higher life forms were patentable subject matter was considered, because if the higher life forms were patentable subject matter, it would be unnecessary to pass the *Plant Breeders' Rights Act*.[168]

The majority and the dissent in *Harvard College* discussed the issue whether genetically modified animals such as the oncomouse should be protected under specific laws like the *PBRA*. The majority held that legislation similar to *PBRA* might be suitable to protect the oncomouse, while the dissent disagreed with this idea.

1.2 A case about the breeding plants and *sui generis*-

***Pioneer Hi-Bred v. Canada (Commissioner of Patents)*[169]**

In *Pioneer Hi-Bred*, the patent applicant applied for a patent on a soybean variety, which is planted naturally by cross-breeding methods to combine three known varieties in order to create the new soybean variety.[170] The Supreme Court of Canada concluded that there were two legal issues to be addressed. First, the Court considered whether higher life forms created by the cross-breeding method could be granted a patent as an 'invention' under s. 2 of the *Patent Act*.[171] Second, the Court had to determine whether there was sufficient disclosure of the invention under s. 36 (1) of the *Patent Act*.[172] The Supreme Court held in this case that the cross-breeding soybean was not patentable subject matter because the soybean varieties of Pioneer Hi-Bred relied heavily on the

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[167] *Harvard College, supra* note 4 at para. 188.
[168] *Ibid.*, at para. 189.
[169] *Pioneer Hi-Bred v. Canada (Commissioner of Patents)* [1989] 25 C.P.R. (3d) 257 [hereafter cited as *Pioneer Hi-Bred.*]
[170] *Ibid.*, at para. 2.
[171] *Ibid.*, at para. 10.
[172] *Ibid.*

laws of nature.[173] The precedent cases in Canada have never granted a patent for this method and the courts have considered living organisms produced from the laws of nature to be only discovery.[174] The Court found that the patent application did not provide enough disclosure of the invention for a person skilled in the art of reproducing the invention; therefore, the Court rejected the patent application.[175] However, the Court did not address the issue whether genetically engineered inventions such as soybean varieties were patentable subject matter. The majority of the Supreme Court of Canada, in a judgment written by Lamer J., distinguished the two types of genetic engineering. The first type is cross-breeding between different species or varieties to create better varieties.[176] The second method, which is the recombinant DNA technology, is the modification of genetic code.[177] The latter affects the entire genome of living organisms and the new modified genes are the result of human intervention.[178] Lamer J. concluded that the soybean variety fell within the first type of genetic engineering.[179] Pioneer Hi-Bred acquired the new soybean variety by hybridization by combining different soybean plants in order to obtain a desirable soybean variety.[180] Pioneer Hi-Bred claimed that they manipulated the reproduction of the soybean in the creation of the new soybean variety; however, Lamer J. opined that Pioneer Hi-Bred's manipulation was the laws of nature and not invention. [181] Moreover, Lamar J. held that the cross-breeding method used by

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[173] *Ibid.*, at para. 17.
[174] *Ibid.*, at para. 19.
[175] *Ibid.*, at para. 36.
[176] *Ibid,* at para. 15.
[177] *Ibid.*
[178] *Ibid.*
[179] *Ibid.*, at para. 17.
[180] *Ibid.*
[181] *Ibid.*, at para. 19.

Pioneer Hi-Bred was not non-obvious because a person skilled in the art can easily follow the method.[182] Although Lamer J. distinguished the two kinds of genetic engineering, Lamer J. did not consider whether the inventions created by the change of the genetic code of the living organisms according to the second type of genetic engineering were patentable subject matter. Therefore, the issue whether genetically modified higher life forms are patentable subject matter had to await discussion in *Harvard College*.

2. The majority opinion in the creating the *sui generis* system like the *PBRA* for the oncomouse.

According to Bastarache J., the enactment of the *PBRA* means that Parliament did not recognize that cross-bred plants, which are higher life forms, are patentable subject matter.[183] Furthermore Bastarache J. stated that "it is reasonable to assume that Parliament would choose to protect these [higher] life forms through legislation other than the *Patent Act* or through an amended *Patent Act* that is better suited to the subject matter."[184] However, Bastarache J. stated that the *PBRA* did not extend to animal life forms because the *PBRA* protects merely plants and plant varieties.[185] As a result, the issue whether the animal life forms are patentable subject matter is still unsolved.[186] According to Bastarache J's opinion, the *PBRA* is likely to be an appropriate solution to protect plants and plant varieties rather than the *Patent Act*.[187] Implicitly, genetically modified animals might need the same kind of regulation for intellectual protection.

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[182] *Ibid.*, at para. 31.
[183] *Harvard College, supra* note 4 at para. 189.
[184] *Ibid.*, at para. 189.
[185] *Ibid.*
[186] *Ibid.*, at para. 193.
[187] *Ibid.*, at para. 194.

Furthermore, the dissent in *Chakrabarty*, written by Brennan J., argued that the U.S. *Plant Patent Act* and the *Plant Variety Protection Act*, which were enacted in 1930 and 1970 respectively, demonstrate that the Congress has solved the problem of the patentability of life forms such as plants and plant varieties by providing some kind of intellectual property protection outside the *Patent Act*.[188] Furthermore, both *Acts* indicate the Congress's intention in excluding living organisms other than plants from patentability; as a consequence, bacteria as living things were also excluded.[189] Brennan J. further argued that if the Congress intended to include living organisms to be patentable subject matter under the *Patent Act*, the 1930 and the 1970 Acts would not exist.[190]

Remarkably, in *Chakrabarty*, Brennan J. construed the existence of both *Acts* more strictly than that of the majority in *Harvard College* because the majority in *Harvard College* accepted that lower life forms such as bacteria are patentable subject matter.

3. The dissent opinion in the creating a *sui generis* system similar to the *PBRA* for the oncomouse

On the other hand, Binnie J. argued that the *Plant Breeders' Rights Act* was not a proper place to solve the problem of the patentability of higher life forms because the application of the *PBRA* is too narrow.[191] Binnie J. reasoned that the *PBRA* provided narrower rights than the patentee's exclusive rights under the *Patent Act*. In addition, the

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[188] *Chakrabarty, supra* at note 5.
[189] *Ibid.*
[190] *Ibid.*
[191] *Harvard College, supra* note 4 at para. 61.

breeders' rights under the *PBRA* cannot prohibit others from developing different varieties from protected plants, and others can use seeds from protected plants without violating the plant breeders' rights.[192] Moreover, Binnie J. argued that the *PBRA* was not in conflict with the *Patent Act*, and the existence of the *PBRA* does not mean that living organisms are excluded from patentability.[193] Rothstein J.A., who wrote for the majority in *Harvard College* in the Federal Court of Appeal, argued this issue in the same way as Binnie J. in that the intellectual protection under the *PBRA* is narrower than that under the *Patent Act* since the *PBRA* provides protection for plants and plant varieties which are created by the cross-breeding method, which rely merely on the 'laws of nature.'[194] The *PBRA* should not be used to imply that living organisms are excluded from patentability. If the inventions do not rely solely on the 'laws of nature,' but the combination between human ingenuity and the 'laws of nature,' the inventions should not be barred from patent protection.[195]

4. The analysis of the *PBRA*

According to the arguments raised by the majority and the dissent in *Harvard College*, I believe that the existence of the *PBRA* does not mean that the *Patent Act* cannot be applied to higher life forms. The *PBRA* was issued in order to protect inventions which heavily rely on the 'laws of nature' such as the cross-breeding method and selective breeding method. As a consequence, if there is no legislation such as the *PBRA*, plant breeders will face difficulty due to the lack of intellectual protection for their

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[192] *Ibid.*
[193] *Ibid.*
[194] *Fed. Court .Appl., supra* note 90 at para. 113.
[195] *Ibid.*

inventions. However, inventions which are created by the combination between the ingenuity and the 'laws of nature' should not be excluded from patentability. The 'laws of nature' play their role in almost every invention. Therefore, even though human intervention and the 'laws of nature' are equally important in the creation of inventions such as genetically modified plants, such inventions should not be barred from obtaining patent protection because the 'laws of nature' alone cannot be used to create such inventions. However, if the inventions largely or solely rely on the 'laws of nature,' the inventions might not be protected under the patent law, unless those inventions are plants or plant varieties which could receive protection under the *PBRA*.

Both cross-bred plants and the oncomouse rely on the 'laws of nature.' While the 'laws of nature' are involved in almost every invention, the degree of the operation of the 'laws of nature' is different in each invention. For cross-breeding and selective breeding method, the degree of the operation of the 'laws of nature' is much more than the inventions invented by the recombinant DNA technology. In the cross breeding method and the selective breeding method, human manipulation does not have much involvement in the creation of an invention. The resulting inventions from both breeding methods still come from the rule of the 'laws of nature'. Humans just combine the species of plants or animals without the ability to control the genes or cells of breeding plants or animals including their characteristics. As a result, the breeding plants or animals cannot be absolutely controlled to carry the desired genes and cells because the technology itself relies on the 'laws of nature.'

On the other hand, the degree to which the 'laws of nature' operate in recombinant DNA technology is less than that of the cross breeding method and the selective breeding method. The recombinant DNA technology does not rely on the 'laws of nature,' except for the growth of the plants or animals. Scientists are able to manipulate genes and cells to acquire desired genes and cells. Scientists can control the animals and their offspring to carry the desired genes and cells in every production and reproduction of the plants and animals. As a consequence, the plants or animals invented by the recombinant DNA technology such as the Oncomouse should be patentable subject matter because the 'laws of nature' always operate in every invention. However, if an invention relies heavily on the 'laws of nature' such as the cross breeding method and the selective breeding method, such invention should not receive patent protection. In other words, animal and plant life forms which are created by the 'laws of nature' or created by the cross breeding method and the selective breeding heavily relying on the 'laws of nature' will not receive any kind of intellectual property protection because they do not fit within the definition of 'composition of matter' under the *Patent Act* and there is no intellectual property protection for plants and plant varieties.

The existence of the *PBRA* poses some problems for advocates of the patentability of the oncomouse. The establishment of a new statute was necessary to provide intellectual protection in plant breeds but it is unnecessary for inventions like the oncomouse because the oncomouse and its creating method are able to meet patent criteria. Unlike plant breeds and plant varieties, the oncomouse does not have difficulty in the written description. The enactment of a *sui generis* system for the oncomouse and

like-inventions will not be useful because there will be too many legislations to cope with intellectual protection for the oncomouse. Moreover, the legislation will be out of date when there is a new and advanced technology in the creation of animals. The broad interpretation of the words of the *Patent Act* will be the most appropriate solution for this issue.

Another problem concerning a *sui generis* system or specific legislation such as the *PBRA* is that the specific legislation designed to protect inventions such as higher life forms might subsequently become obsolete. For example, the *Semiconductor Chip Protection Act*, which was adopted to protect the technology current at that time of the enactment of the Act, became obsolete later on.[196] In addition, Binnie J., in dissenting, tends to anticipate the same result; as a consequence, Binnie J. suggests that the *Patent Act* should be defined broadly to include unforeseeable inventions.[197]

In sum, the amendment of the *Patent Act* or the passage of specific legislation in order to protect higher life forms may not be an appropriate solution because the technology has been developing rapidly. The most appropriate solution for this problem is that the words of the *Patent Act* should be interpreted broadly enough to cover unanticipated or unforeseeable inventions.

Conclusion

In *Harvard College*, the majority and the dissent disagree in the issuing of the *sui generis* to protect an invention like the oncomouse. I agree with the dissent's opinion in *Harvard College* in that the *sui generis* system is unnecessary if the oncomouse is

[196] Dan L. Burk, ``Reflections in a Darkling Glass: A Contemplation of the Harvard College Decision`` (2003) 39 Canadian Business L.J. 229-230.

patentable subject matter. The issuing of a specific regulation to cope with the invention like the oncomouse only will be highly likely to become obsolete subsequently. However, Canada may not be ready to grant a patent on a genetically modified animal due to the lack of regulatory framework. In the next chapter, I shall therefore discuss the regulatory framework that should be considered, if Canada decides to grant a patent on genetically modified animals.

Chapter 4

Regulatory Framework

Introduction

If Canada decides to provide patent protection for higher life forms such as genetically modified animals and plants, there are certain regulatory framework that should be considered in order to balance the public interest and the patent holders' rights. The patent on genetically modified animals relates to a complicated issue such as a 'life' patent, and also expands to some kinds of animals which have mammalian cell lines similar to humans. Therefore, the regulatory framework is suggested to prevent immoral patents and to solve problems in biotechnological research and development and to balance the public's interest and the patentees' rights. In this part, I would like to suggest some provisions that should be inserted in the *Patent Act*. I separate the regulatory framework into two parts. The first part is the regulatory framework which concerns the prohibition of other people from using the patented invention without license or permission from the patentee. The first part consists of the research and experimental use exception, the farmer's privilege, and innocent bystander defense. The second part is the regulatory framework which are additional requirements intending to prevent immoral patents. The second part will discuss the 'ordre public' and morality.

1. The regulatory framework that prohibits other people from using the patented invention without permission.

1.1 The Research and Experimental Use Exception (REUE)

A patentee has exclusive rights conferred by the *Patent Act* in "making,

constructing and using the invention and selling it to others to be used."[198] If scientists conduct research and experiment on the patented inventions without the patentee's permission, they may infringe the patentee's exclusive rights. Scientists need to use the patented inventions in order to develop new inventions. Due to the lack of Research and Experimental Use Exception (REUE), universities and other researchers fear they might infringe patentees' rights in their research. The scientists may have to pay license fees in return for using the patented inventions in their research and experiment. The cost of using a patented invention may be so exorbitant that the scientists cannot afford it.[199] The consequence of this situation is the decrease of biotechnological investment and the withholding of experiments and research.[200] According to the Centre for Intellectual Property Policy (CIPP) Final Report on Genetic Patents and Health Care in Canada: An International Comparison of Patent Regimes of Canada and Its Major Trading Partners, there is empirical evidence that clinical researchers believe patents obstruct research and experiment.[201] Also, there are reports from directors of clinical laboratories that they were threatened by patentees to stop conducting research or paying license fee.[202] This problem leads to fear of patent infringement among scientists.

If patents on biotechnological inventions such as the Oncomouse are allowed, the REUE is required. This exception will eliminate the fear of patent infringement among

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[198] ***Patent Act,*** R.S.C. 1985, c. P-4, s. 42.
[199] The Centre for Intellectual Property Policy, "Final Report: Genetic Patents and Health Care in Canada: An International Comparison of the Patent Regimes of Canada and Its Majors Trading Partner" (January 2005), online: Canada Biotechnology Advisory Committee < http://cbac-cccb.ca/epic/site/incbac-cccb.nsf/vwapj/CIPP_FINAL_report_e.pdf/$FILE/CIPP_FINAL_report_e.pdf>. [hereinafter cited as CIPP Report] at 24. Last visit: 13 March 2008.
[200] *Ibid.*
[201] *Ibid.*
[202] *Ibid.*

scientists conducting research. With the REUE, experimental research, especially in the biotechnology field, will be greatly increased since scientists will be able to work without fear of infringement. The Intellectual Property Modeling Group (IPMG) is an expert group developed by the Centre for Intellectual Property Policy (CIPP) on advanced research organization concerned with intellectual property and biotechnology. In the Final Report, the IPMG recommended that the REUE as well as the CBAC' s recommendation be contained in the patent law.

The CBAC or Canadian Biotechnology Advisory Committee is a governmental organization which provides recommendations on the legal issues relating to biotechnology.[203] The CBAC Report in Patenting Higher Life Forms also recommends the REUE.

The REUE is established in the patent laws of many European countries, Iceland, Japan, Korea, Mexico, Norway and Turkey.[204]

In Europe, Article 27 (b) of the *Community Patent Convention (CPC)* provides that "The rights conferred by a Community Patent shall not extend to: ... (b) acts done for experimental purposes relating to the subject-matter of the patented invention."[205] Article 27 (b) clearly includes the research and experimental use exception within the *CPC*. Even though Article 27 (b) of the *CPC* has not come into force yet, many European

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[203] Canadian Biotechnology Advisory Committee, online: Canadian Biotechnology Advisory Committee <http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/Home.>. Last visit: 11 March 2008.

[204] Chris Dent, Paul Jensen, Sophie Waller and Beth Webster, "Research Use of Patented Knowledge: A Review" (17 March, 2006), online: Organization for Economic Co-operation and Development <http://www.oecd.org/dataoecd/15/16/36311146.pdf. >. [hereinafter cited as OECD Workshop Paper]. Last visit: 28 February, 2008.

[205] European Community and European Office, "CPC- Convention For The European Patent For The Common Market," online: European Community and European Office <http://legis.obi.gr/ESPACEDVD/legal_texts/LAWS_E/eu_cvn04.htm.> Last visit: 28 February 2008.

Union members has incorporated the provision within their patent laws.[206] For example, Germany provides for the REUE within the *German Patent Act*. Article 11.2 of the *German Patent Act* states that "The rights conferred by the Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention."[207] Moreover, s 3 (3) of the Iceland *Patent Act* 1993 states that "The following are excepted from the (patentee's) exclusive rights ... use of the invention for experiments which relate to the invention itself ..."[208] In Japan, similar provision is also found within the patent law. According to s 69 (1) of Patent Law of Japan, "The effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research."[209] Likewise, Article 22 of the Industrial Property Law of Mexico states that "The right conferred by a patent shall not have any effect against: (i) a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented..."[210]

However, the existence of a REUE is still vague under Canadian patent law. Moreover, the Supreme Court of Canada had an opportunity to consider whether a REUE

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[206] Craig Smith, "Experimental Use Exception to Patent Infringement—Where Does Australia Stand?" (2003) 50 Intellectual Property Forum 18.
[207] Heinz Goddar, "The Experimental Use Exception : A European Perspective," online: CASRIP Publication Series: Reconciling Int'l Intellectual Property <http://www.law.washington.edu/CASRIP/Symposium/Number7/1-Goddar.pdf.>. at 10. Last visit: 13 April 2008.
[208] DNA Patent Database, " Research Exemption Table," online: Georgetown University <http://dnapatents.georgetown.edu/resources/Research%20Exemption%20Table.pdf.>. [hereinafter cited as Research Exemption Table]. Last visit: 13 April 2008.
[209] *Ibid.*
[210] *Ibid.*

is available under Canadian law, but decided to focus instead on compulsory licensing in a case involving research and experiments based on previous patented inventions.[211]

Now the challenge is how to protect patentees' rights while encouraging scientists to develop further innovation. The CBAC recommends that the *Patent Act* should provide the following statement:

"*It is not an infringement of a patent to use a patented process or product either:*

(a) privately and for non-commercial purposes, or

(b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process."[212]

The CBAC also explained that the words 'to investigate its properties, improve upon it, to create a new product or process' were designed to clarify that the exception covers merely the studying of the 'nature of the invention.'[213] Another issue is that the CBAC chooses to use the word 'to study' rather than 'experimental use' because the word 'to study' is broader than "experimental use" in that it includes the studying of patented inventions in classrooms.[214]

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[211]The CBAC Report 2002, *supra* note 98 at 14. *Micro Chemicals v. Smith Kline & French Inter-American Corp.* (1971) 2 C.P.R. (2d) 193 CC. The case is about the infringement of patented invention. Micro Chemicals Ltd. had used the patented invention owned by Smith Kline & French Inter-American Corp. for research purpose. The Court decided that the action of Micro Chemicals, the use of patented invention in the making of medicine by the defendant was not an infringement, because it is the compulsory licensing in the use of patented medicine for research purpose.

Note: The compulsory license is the rights authorized to one or more parties by Commissioner of Patents in the production of invention under some situation, which make an action not become patent infringement. (cited from Canadian Intellectual Property Office, "A Guide to Patents: Glossary," online: Canadian Intellectual Property Office <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/pat_gd_gloss-e.html > Last visit: 11 March 2008).

[212]The CBAC Report 2002, *supra* note 98 at 16.

[213] *Ibid.*

[214] *Ibid.*

Notably, the concept of REUE according to the CBAC' s recommendation is very close to the 'fair dealing' of copyrights. Pursuant to s. 29 of the *Copyright Act*, "fair dealing for the purpose of research or private study does not infringe copyright."[215] However, 'fair dealing' faces the question of to what degree research or private study should be extended since the word 'study' includes not only scholars and students but also private companies and their employees.[216] Consequently, the companies might use 'fair dealing' as an excuse for their own research and again private companies may receive financial benefits rather than the public sector unless the 'fair dealing' excludes commercial- purpose activity.[217] Incidentally, in the United States, employees and individuals are not allowed to copy journal articles to use in their research if they can find or buy the copyright works.[218] In Canada, there is also a case similar to this example in *CCH Canadian Ltd. v. Law Society of Upper Canada*.[219] In *Cancopy*, one of arguments arising before the Court was whether the custom photocopy service of legal materials provided by the Great Library of the Law Society of Upper Canada for its member is the infringement of copyrights of publishers, which are CCH Canadian Ltd., Thomson Canada Ltd. and Canada Law Book Inc.[220] The Court held that the custom photocopy of the Law Society did not infringe the copyrights of the publishers.[221] The Court determined that the custom photocopy of the legal materials was for the purpose of

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[215] ***Copyright Act***, R.S.C. 1985, c. C-42, s. 29.
[216] Vaver , *supra* note 40 at 104.
[217] *Ibid.*
[218] *Ibid.*
[219] *CCH Canadian Ltd. v. Law Society of Upper Canada*, [2004] 1 S.C.R. 339 [hereinafter cited as *Cancopy*].
[220] *Ibid.*
[221] *Ibid.*

research, and therefore, was 'fair dealing' according to s. 29 of the *Copyright Act*.[222] The Court interpreted the purpose of research that the "research for the purpose of advising clients, giving opinions, arguing cases, preparing briefs and factums is "research."[223] Even though lawyers conduct research for profit, the lawyers' action is 'fair dealing' within s. 29 of the *Copyright Act*.[224] In conclusion, in Canada, the *Cancopy* case clarifies that the purpose of research does not relate to profits. The scope of 'fair dealing' is fairly broad under the *Copyright Act*. It should be noted that in *Cancopy* the photocopy service is the library service not private photocopy service. Under the *Canadian Copyright Act*, "educational institutions, libraries, archives and museums are specifically exempted from copyright infringement in certain circumstances."[225] If an individual makes a photocopy of a copyright work from a private photocopy service, he/she might infringe the copyright.

If Parliament decides to establish the REUE in or outside the *Patent Act*, problems such as the nature of the word 'study' (as suggested in the CBAC Report) would need to be solved.[226] The scope of 'study' can be illuminated by judicial and scholarly interpretation of the 'fair dealing.' However, it is noted that the CBAC suggests that the REUE should not include research for commercial purposes.

In summary, the research and experimental use exception should be inserted in the patent law in order to encourage the development of biotechnology. Furthermore, the grant of patents on biotechnological inventions such as the Oncomouse will not bar other

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[222] *Ibid.*
[223] *Ibid.*
[224] *Ibid.*
[225] *Ibid.*
[226] Vaver, *supra* note 40 at 104.

scientists to access to the technology. Because of the lack of the REUE, if the Court grants a patent on inventions which have medical benefits such as the oncomouse, other scientists will have difficulty to use the patented inventions for their research due to the fear of patent infringement. The REUE will eliminate this fear.

1.2 The farmers' privilege

There is a concern for the agricultural community and the food supply if the patents on higher life forms are allowed.[227] Farmers are concerned that they will not be protected if the patents on the higher life forms such as the oncomouse are allowed. They will not be able to use patented animals for agriculture because they cannot afford the license fees. Furthermore, farmers fear that they may use genetically modified animals without the knowledge of the existence of patents on those animals. The result is they may be sued because of the act of patent infringement. After the court's decision in *Monsanto*, the need for the farmers' privilege increases. In *Monsanto*, the court held that Schmeiser, a farmer in Saskatchewan, infringed Monsanto's patent rights by using modified genes and cells of canola plants because Canada does not have protection for farmers.

Under Canadian patent law, there is no requirement that defendants in patent infringement cases know or should have known of the existence of the patented inventions.[228] Therefore, farmers fear that they might be sued by patentees, when the farmers did not know that the patented inventions are present on their farms.

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[227] The CBAC Report 2002, *supra* note 98 at 13.
[228] *Ibid.*, at 14.

The farmer's privilege exception is one of the solutions proposed by the CBAC to address this concern. The CBAC recommends that a farmer's privilege provision be included in the *Patent Act*. The CBAC also suggests that the Act should specifically allow farmers to 'save and sow' seeds from patented plants or to breed patented animals, as long as the offspring are not traded as 'commercial propagating material' or in a way that destroys the 'commercial value' of the patented plants and animals.[229] If the farmer's privilege is introduced into the patent law both the farmers' rights and food resources would be protected.[230] Canada, therefore, would encourage biotechnology and be better able to maintain food resources and agricultural businesses.

The European Community has established a farmer's privilege in its patent law which "allows a farmer to reproduce non-human animals and some kinds of plants for the farmers' own use, without the permission of the patentee."[231] Canada does not have such a provision in its patent law since higher life forms are still unpatentable subject matter.[232] Canadian farmers are somewhat protected by a farmer's privilege under the *Plant Breeders' Rights Act*.[233] However, the protection under the *Plant Breeders' Rights Act* is insufficient to apply with the case of the patents on genetically modified plants and animals. In order to provide the farmers' privilege, Parliament should examine the relationship among the *Patent Act*, the *Plant Breeders' Rights Act*, and the *Animal Pedigree Act*.[234] "While the *Plant Breeders' Rights Act* provides protection over certain

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[229] *Ibid.*, at 12.
[230] *Ibid.*, at 13.
[231] *Ibid.*
[232] *Ibid.*
[233] *Ibid.*
[234] *Ibid.*

varieties of plants to the inventor of these varieties, the *Animal Pedigree Act* provides protection for the marketing of particular breeds of animals, which could include transgenic animals."[235] The CBAC suggests that Canada might adopt a farmers' privilege similar to that of Europe, but the scope of animals should be broader to include genetically modified animals.[236]

If the *Patent Act* is amended to provide the farmer's privilege tagging along with the innocent bystander defense, this problem will be solved. The best model of the farmer's privilege should be the combination of the European perspective and the CBAC' s recommendation. The farmer's privilege should provide protection for farmers in the production and reproduction of the patented plants and animals, and the protection should expand to include the genetically modified animals.

1.3 Innocent bystander defense

The innocent bystander exception is another recommendation from the CBAC. The reproduction of a patented invention without permission from patentees is infringement of the patent. The patentees are able to sue for patent infringement or to stop the action of infringement or both.[237] Due to the self-replicating characteristic of genetically modified plants and animals, it is possible that a genetic invention could escape from its confining location and reproduce itself on the property of a person who is not the patent holder. This would have serious repercussions for the individuals on whose land the reproduction occurs.

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[235] *Ibid.*
[236] *Ibid.*
[237] *Ibid.*

Canadian patent law does not have provision for defendants to prove that they knew or would have known about the action of infringement.[238] The CBAC recommends that the *Patent Act* include a provision that "the usual presumption concerning infringement can be rebutted in respect of inventions capable of reproducing, such as plants, seeds and animals."[239] This exception is important for the farmer, especially after the *Monsanto* case, in which the Court decided that the use of genetically modified seeds by a farmer is the act of patent infringement. The concern about patent infringement by farmers increases due to the lack of farmers' protection.

Another concern is that there is no judicial decision whether "a patentee [should] be able to claim patent protection for the offspring produced by mating the patented animal with a non-patented animal."[240] However, one commentator suggested that "patent protection should only cover the progeny of patented animals which display all the characteristics of the animal claimed in the patent."[241] In order to solve the problem of patent infringement in this case, the innocent bystander defense is recommended for Canadian patent law.

Even though Canada does not have a provision about an innocent bystander defense, Norman Siebrasse suggests 4 models of innocent bystander defense to be contained within the Canadian patent law:

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[238] *Ibid.*, at 14.
[239] *Ibid.* , at 13.
[240] Morin, *supra* note 2 at 191.
[241] *Ibid.*

The models recommended by Siebrasse influenced the Supreme Court's decision in *Schmeiser*. Siebrasse view is that innocent persons who unintentionally use genetic inventions infringe the patentees' rights.

1. A farmer intends to use the genetic invention without the patentee's permission and receives benefits from the invention.[242] In this case, the farmer has to pay damages to the patentee because the farmer knows the existence of the patented invention and receive benefits from it.[243] Regardless the innocent bystander defense, the farmer has to compensate to the patentee because the received benefits.[244]

2. A farmer did not know the patented inventions came onto his land and unintentionally continues to use the inventions but received benefits from the patented inventions.[245] Generally, the patented crops require special treatment such as designated herbicide. However, if the farmer treated the patented crops the same way as the regular crops and s/he did not receive benefits from the patented crops, the farmer does not have to pay damages to the patentee. If there is an innocent bystander defense, the farmer would prove that s/he is innocent because of the

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[242] Norman Siebrasse, "The Innocent Bystander Problem in the Patenting of Higher Life Forms," (2004) 49 McGill L.J. 354.
[243] *Ibid.*
[244] *Ibid.*
[245] *Ibid.*

lack of the intention to use the patented inventions.[246] The farmers have to pay for benefits they received from the use of patented inventions.[247]

3. This case is the similar case to *Monsanto*. The farmer uses the patented inventions without knowledge of the existence of patent inventions, but continues to use them after the farmer knew the existence of patented inventions.[248] However, the farmer did not receive benefits from the patented inventions. Schmeiser is an "intentional non-benefiting" user. In *Monsanto*, the Court of Appeal held that an innocent person should be relieved from liability, if s/he did not receive benefits from the patented inventions.[249] Nevertheless, the Court did not determine whether an innocent person who lacks intention to use the patented inventions but benefits from the patented inventions is liable for the patent infringement.[250] Siebrasse opines that it is possible to punish the farmer by imposing fines or punitive sanction for the propagation of the patented crops with intention.[251]

4. The final case is called "an unintentional non-benefiting farmer."[252]The farmer in this case uses the patented crops without knowing the existence of the patented inventions.[253] Moreover, the farmer did not

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[246] *Ibid.*
[247] *Ibid.*
[248] *Ibid.*
[249] *Ibid.*
[250] *Ibid.*
[251] *Ibid.*
[252] *Ibid.*, at 355.
[253] *Ibid.*

receive benefits from the patented inventions.[254] In *Monsanto*, the Court of Appeal wanted to punish the intentional non-benefiting farmer, while releasing the unintentional non-benefiting farmer.[255] Siebrasse proposed that the best approach is the consideration of benefits in the case of unintentional users, while a punitive sanction is considered when dealing with the intentional user.[256]

These 4 models are important in the consideration of the innocent bystander, if Canada will establish the innocent bystander defense subsequently.

Other jurisdictions such as England, Australia, New Zealand and the United States recognize the innocent bystander provision within their patent laws.[257] Under § 35 U.S.C. 287, the statute contains that:

> (a) Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this cannot be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be

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[254] *Ibid.*
[255] *Ibid.*
[256] *Ibid.*
[257] *Ibid.*, at 358.

recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.[258]

Subsection 62 (1) of the *UK Patent Act*, provides as follows:

In proceeding for infringement of a patent damages shall not be awarded, and no order shall be made for an account of profits, against a defendant or defender who proves that at the date of infringement he was not aware, and had no reasonable grounds for supposing that, the patent existed; and a person shall not be taken to have been so aware or to have had reasonable grounds for so supposing by reason only of the application to the product of the word "patent" or patented," or any word or words expressing or implying that a patent has been obtained for the product, unless the number of the patent accompanied the word or words in question.[259]

In Australia, the *Australia Patent Act 1990* s. 123 states that

(1) A court may refuse to award damages, or to make an order for an account of profits, in respect of an infringement of a patent if the defendant satisfies the court that, at the date of the infringement, the defendant was not aware, and had no reason to believe, that a patent for the invention existed.

(2) If patented products, marked so as to indicate that they are patented in Australia, were sold or used in the patent area to a substantial extent before the date of the infringement, the defendant is to be taken to have been aware of the existence of the patent unless the contrary is established.[260]

Finally, s. 68 of the *New Zealand Patent Act 1953* also provides innocent bystander provision as follows:

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[258] United States Patent and Trademark Office, "§35 U.S.C. 287 Limitation on Damages and other Remedies ; Marking, and Notice- Patent Laws," online: United States Patent and Trademark Office <http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_287.htm. >. Last visit: 13 April 2008.

[259] UK Intellectual Property Office, "The *Patent Act* 1977" online: UK Intellectual Property Office <http://www.ipo.gov.uk/patentsact1977.pdf. > Last visit: 13 April 2008.

[260] Australian Legal Information Institute, "Commonwealth Consolidated Act: *Patent Act 1990*-SECT 123" online: Australian Legal Information Institute <http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/s123.html >. Last visit: 13 April 2008.

(1) In proceedings for the infringement of a patent, damages or account of profits shall not be awarded against a defendant who proves that at the date of the infringement he was not aware, and had no reasonable ground for supposing, that the patent existed; and a person shall not be deemed to have been aware or to have had reasonable grounds for supposing as aforesaid by reason only of the application to an article of the word "patent", "patented", or any word or words expressing or implying that a patent has been obtained for the article, unless the word or words are accompanied by the words "New Zealand" or the letter "NZ" and by the number of patent.[261]

The raised innocent bystander provisions in the U.S., UK, Australia and New Zealand are similar. They use a marking requirement on the patented products by using the word or words such as "patent" or "patented" to solve the problem of an innocent bystander in the first level. Even though the words of the UK and New Zealand provision are almost similar, the interpretation of UK legislature is broader than New Zealand since the defendant can prove their lack of knowledge and innocence.[262] Moreover, Australia's provision provides the broadest protection because a defendant can prove his innocence whether or not he knew or ought to have known the existence of the patented products.[263] The US provision about the innocent bystander defence is the narrowest compared to other countries because if the patented products are marked, the defendant cannot prove their innocence or the lack of knowledge.[264]

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[261] Interim Web Site of New Zealand Legislation, "*Patent Act* 1953," online: Interim Web Site of New Zealand Legislation <http://interim.legislation.govt.nz/libraries/contents/om_isapi.dll?clientID=85231&infobase=pal_statutes.nfo&jd=a1953-064%2fs.68&record={78E30}&softpage=DOC#JUMPDEST_a1953-064/s.68>. Last visit: 13 April 2008.
[262] Siebrasse, *supra* note 242 at 359.
[263] *Ibid.*
[264] *Ibid.*

In Canada, patent holders can mark their patented products but they cannot use it to prove the knowledge of a defendant. In my opinion, Canada should adopt the UK and Australia's innocent bystander provisions to be applied within the Canadian patent law. The marking requirement should be a factor to prove the innocence of a user, not determinative. In sum, I believe that the innocent bystander defence should be provided within the *Patent Act* in order to protect innocent persons.

To protect the public while balancing patentees' rights, additional regulatory framework is required in the *Patent Act* in order to prevent immoral patents such as patents on humans. The regulatory framework is covered in the following section.

2. The additional rules required to prevent immoral patents

The 'ordre public' or morality exception

There is a concern that the grant of patents on genetically modified animals could lead to patents on other living organisms containing mammalian cell lines including humans. In addition, some groups of people argue that patents on genetically modified animals cause animal suffering and violate animals' rights. Therefore, an 'ordre public' or morality exception is recommended in order to prevent immoral patents.

The concept of 'ordre public' or morality exception was first introduced by the *European Patent Convention* (*EPC*).[265] According to the European patent laws, the concept of 'ordre public' is generally understood as the protection of public safety and

[265] Morin, *supra* note 2 at 158.

the safety of the physical assembly of individuals as a part of community.[266] Inventions which are likely to be dangerous to people and environment are against 'ordre public.'[267] On the other hand, the concept of morality depends on social beliefs.[268] Morality is established from people in community believing that some behaviors are acceptable or unacceptable; therefore, morality may be different in each society due to different cultures.[269] The *Biotech Directive,* which is established by the Council of European Union and the European Parliament in order to harmonize patent law system among the members of the *European Patent Convention*[270], also affirms the 'ordre public' and morality exception by inserting the exception into the regulation of the *Directive.* Article 6 of the *EC Directive 98/44* provides that:

"*1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to 'ordre public' or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

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[266] Eliza Saunders & Jasmina Mutabzija, "Patentability, *Ordre Public* and Morality: The Case of Inventions Invovling Human Embryonic Stem Cells—an EU, US and Australian Perspective" (2004) 59 Intellectual Property Forum 14.
[267] *Ibid.*
[268] *Ibid.*
[269] *Ibid.*
[270] *Ibid.*

(d) *processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*"[271]

Most of the *European Patent Convention (EPC)* members are also the member nations of the E. U. In 1999, the European Patent Office implemented the *EPC* by introducing Rule 23 d which is similar to Article 6.2 of the *Directive*.[272]

There was a problem about whether the Oncomouse, whose genes were modified, was patentable subject matter since it might be against the *Directive* and *EPC* provision respecting 'ordre public' or morality. The EPO had granted a patent on the Oncomouse on April 3, 1992, although the *European Patent Convention* has 'ordre public' and morality exception provision. The European Patent Office (EPO) determined that the patent on the Oncomouse was not contrary to 'ordre public' and morality when weighing the public interest and the animal suffering.

The Examining Division concluded that the Oncomouse was not an animal variety and would not violate public order and morality since the mouse provides medical benefits outweighing the suffering of the mouse; and therefore, the oncomouse was

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[271] David Thomas & Georgina A. Richard, " The Importance of Morality Exception under the European Patent Convention: The Oncomouse case Continues..." (2004) 26 European Intellectual Property Review 99.

[272] *Rule 23d* of the *EPC* states that "Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes." (http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/r23d.html) last visit: 5 March 2008.

patentable subject matter.[273] "The Examining Division held that non-human 'mammals' and 'rodents' fall within a higher taxonomic rank than 'animal varieties' and therefore do not fall within the terms of article 53(b) of the *EPC*."[274] The most recent *Directive* affirms that inventions such as genetically modified plants and animals, which are composed of or contain biological material, are patentable if the inventions meet the patent criteria.[275] In the grant of a patent on the oncomouse, the Opposition Division determined that Rule 23 d. applied to the invention of the oncomouse even though the oncomouse was invented before Rule 23 d.[276] Even though Rule 23 d. came into force on 1 September 1999 after the grant of a patent of the oncomouse in 1992, the Opposition Division stated that the rule was a part of the previous law.[277]

Rule 23 d. is a regulation which makes the law in the part of the patentability of genetically modified animals complete.

David Thomas and Georgina A. Richards have noted that the term 'substantial medical benefit' in Article 6. 2 of the *EPC* was construed that "the medical benefit must be the alleviation or prevention of a serious condition."[278] If there are no or little medical benefits, the genetically modified animals are not granted patents. For example, in the *Upjohn* case, there is an argument whether or not a mouse used in the experimentation for the treatment of baldness was 'substantial medical benefit.'[279] The EPO rejected the

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[273] Morin, *supra* note 2 at 159.
[274] *Ibid.*
[275] *Ibid.*, at 161-162.
[276] Note: The Oncomouse was granted a patent by the EPO in 1992.
[277] Andrew Sharples and Duncan Curly, Acdermott, Will & Emery, "Harvard oncomouse- the EPO's latest word," online: Pharmalicensing <http://pharmalicensing.com/public/articles/view/1077697164_403c5a8ca1fe1.> Last Visit: 13 May 2008.
[278] Thomas & Richard, *supra* note 271 at 103.
[279] *Ibid.*

patent on the hairless mouse because the patent claim was against morality for the reason that animal suffering outweighed the public interest.[280]

In the United States, there is no provision about 'ordre public' and morality exception within its patent law.[281] Indeed, when the United States Patent and Trademark Office (USPTO) and the Court consider the patent eligibility of an invention, they hardly recognize 'ordre public' and morality. In addition, the United States has no particular exception to exclude human beings from patentability in federal patent law.[282] The USPTO's view is that the patent law is not a place to address ethical and moral concern arising from scientific activities.[283] However, Congress bars some inventions from patentability for the reason that the inventions are against 'national security.'[284]

Nevertheless, the filing of a patent claim over '*a human/non-human chimera*' alerted the USPTO to review a debate over the 'ordre public' and morality exception.[285] Consequently, the USPTO addressed problems about the grant of patents relating to humans that "Congress did not intend to allow patents on human or on creatures that are essentially human when it passed the *Patent Act* in 1952."[286] The USPTO also referred to the 13th Amendment of Constitutional Law that people cannot be expolited.[287] Furthermore, the USPTO expressed the view that the U.S. Patent Courts were concerned about 'ordre public' and morality by interpreting the utility requirement under 35 U.S.C.

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[280] *Ibid.*
[281] Saunders & Mutabjazi, *supra* note 266 at 25.
[282] *Ibid.*, at 24.
[283] *Ibid.*
[284] *Ibid.*
[285] *Ibid.*
[286] *Ibid.*
[287] *Ibid.*, at 26.

§ 101 to exclude from patentability inventions that are "injurious to the well-being, good policy, or sound morals of society".[288] However, the Courts do not usually use the exception to bar inventions from patentability. In 2001, the United States issued the *Utility Examination Guidelines* in order to adjust the utility requirement to the advanced biotechnology. The Utility Requirement requires that "the utility is specific, substantial, and credible."[289] However, the Utility Requirement 2001 concerns about the patents on biotechnological inventions rather than 'ordre public' or morality exception.

In *Harvard College*, the dissent led by Binnie J. recommended that 'ordre public' or morality exception be included within the *Patent Act*. Some people fear that the patents on animals might lead to patents on human beings in the future; therefore, the 'ordre public' or morality exception is suggested to solve this problem.

In addition, Binnie J. mentioned that both *NAFTA*[290] and *TRIPS*[291] provide for an 'ordre public' and morality exception. Therefore, Canada should take this exception into account. Bastarache J. also agreed that an 'ordre public' or morality exception might be another option for Parliament to allow patents on higher life forms.[292]

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[288] *Ibid.*

[289] United States Patent and Trademark Office, "2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement- 2100 Patentability," online: United States Patent and Trademark Office < http://www.uspto.go/web/offices/pac/documents/2100_2107.htm.>. Last visit: 11 March 2008.

[290] Article 1709.2 of *NAFTA Agreement* provides that "A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent." (cited from http://www.worldtradelaw.net/nafta/chap-17.pdf.)

[291] Article 27.2 of *TRIPS Agreement* provides that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law." (cited from http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5.)

[292] *Harvard College, supra* note 4 at para. 182.

3. The analysis of 'ordre public' and morality exception

I agree with the dissenting opinion in *Harvard College* that 'ordre public' and morality exceptions should be established to protect public interests. However, the European perspective on 'ordre public' and morality should be considered in the measure between medical benefits and animal suffering.

The *Directive 98/44/EC* prohibits specific inventions to be patentable such as "the process for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes" because these inventions are against 'ordre public' and morality.[293] Even though the CBAC did not explicitly mention 'ordre public' and morality exception, the CBAC's recommendation is almost close to the specific prohibitions of the *Directive* in Article 6 paragraph 1 and 2. The CBAC 's recommendations about the patentability of the higher life forms is that if higher life forms are patentable subject matter, "human bodies at all stages of development should be excluded."[294] However this exclusion does not include claims over DNA sequences, cell lines or stem cells of human origin because it is unlikely that patentees of these patents will have control over human beings.[295] However, the prohibition on specific inventions should not be too narrow because there might be some future inventions which would be considered against 'ordre public' and morality. In

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[293] Richard Gold & Alain Gallochat, "The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation, and Lesson for Canada, prepared for the Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual property and the Patenting of Higher Life Forms" (2001) online: Canadian Biotechnology Advisory Committee at 3 <http://cbcac-cccb.ca/epic/internet/incbac-cccb.nsf/vaapj/EU_Gov_Protection_e.pdf/$FILE/EU_Gov_Protection_e.pdf> Last visit: 3 March 2008.

[294] The CBAC Report 2002, *supra* note 98 at 11.

[295] *Ibid.*, at 8.

other words, the 'ordre public' or morality exception should leave some space to consider unanticipated inventions in the future.

There is a concern that patents on genetically modified animals would lead to patents on human beings. In dissenting in *Harvard College*, Binnie J. argued that "there is a qualitative divide between rodents and human beings."[296] Moreover, many provisions regarding patents on higher life forms exclude patents on humans such as The *European Patent Convention* and the *Biotech Directive*. The 'ordre public' and morality exception plays an important role in preventing patents on humans or human bodies; therefore, the patent on the oncomouse will not lead to patents on human beings. In addition, the CBAC suggests that if Canada decides to grant patents on genetically modified animals or higher life forms, the patentability of humans or human bodies at any stages should be excluded.[297]

In *Harvard College*, Bastarache J. questioned the dividing line between human and animal in xenotransplantation. Xenotransplantation is a technology which is used to transfer human genes or organs into animals having the same cell line as humans such as pigs for the purpose of organ transplantation.[298] The Animal Alliance of Canada, an intervener, asked a question: "The pig receives human genes. The human receives pig organs. Where does the pig end and the human begin?...".[299] However, there is no conclusion to this question. To solve this problem, the 'ordre public' or morality exception could be considered as to whether the patents on xenotransplantation or

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[296] *Harvard College, supra* note 4 at para. 102.
[297] The CBAC Report, *supra* note 98 at 7.
[298] *Harvard College, supra* note 4 at para. 179.
[299] *Ibid.*

animals carrying human genetic materials will be against an'ordre public' and morality. On the one hand, the patents on animals used in xenotransplantation might be against an 'ordre public' or morality because the animals will be composed (in part) of human genes and the patents will lead to the fear of the control over humans or human bodies. On the other hand, if the patents on genetically modified animals are allowed, why would patents not be allowed on animals used in xenotransplantation? If the medical benefit of the invention outweighs the animal suffering, should a patent be granted respecting the animal? The patent rights confer exclusive rights to the patentees in prohibiting others from making, using, selling or importing the inventions; however, the patent does not provide the ownership of the invention. If patents on animals used in xenotransplantation are allowed, the patents give the patentees merely exclusive rights not complete control over humans or human bodies as well as the patents on DNA sequences or human germ lines. Patents on animals used in xenotransplantation still need time to be considered because it could be or could not be against the 'ordre public' or morality.

Another concern over patents on genetically modified animals is who should assess of the benefits of the patent. This concern is that bioethical expertise is required to consider the issue, and the bioethical expertise may be lacking in the Patent Office and the Courts. In Canada, there is no organization to deal with both legal and ethical issues arising from biotechnological inventions. The Courts do not have expertise in both biotechnology and ethical issues about biotechnology. If there is an establishment of bioethical expertise, the expertise should be neutral and separate from Patent Office and the applicants and inventors. The bioethical expertise should be a special process in

determining the ethical issues about patents on biotechnological inventions if the Commissioner of Patents and the Courts do not have specific knowledge on that issue. The bioethical expertise will be used to determine whether the inventions are against 'ordre public' and morality of society. For example, in *Harvard College*, one of the reasons the Court denied the grant of a patent on the oncomouse is that the lack of regulatory framework such as 'ordre public' and morality indicated higher life forms were unpatentable subject matter. Therefore, the bioethical expertise will address the ethical concerns on the patent on the oncomouse such as the slippery slope to patent on humans.

Conclusion

The regulatory framework provided in this chapter is necessary, if there is a grant of a patent in Canada for creations like the oncomouse. The research and experimental use exception is important to the promotion of technology. The innocent bystander defense and the farmer's privilege will help innocent farmers prove their innocence in the case that they are accused of patent infringement. Finally, the 'ordre public' and morality will exclude harmful inventions from patentability by weighing the public interest and the rights of patentees. According to the discussion of the raised legal issues in previous chapters and the important regulatory framework that should be contained within the *Patent Act* in this chapter, the next chapter will be an attempt to focus on these problems in Thai patent law.

Chapter 5

Thai patent law and biotechnological inventions

Introduction

Thai patent law is adopted from other countries. Thailand does not have the potential to produce genetically modified animals in this level. However, Thailand has capacity to create genetically modified plants. This chapter consists of 3 parts. First, I shall explain the evolution of Thai patent law and general concept of Thai patent law including Thai petty patent law. Second, I will discuss patents on genetically modified animals in Thailand and related legal issues. Finally, I shall discuss the connection between *TRIPS Agreement* and Thailand.

1. The Evolution of the Thai Patent Law

The *Thai Patent Act* was first enacted in 1979.[300] The intention of the Government in the passage of the *Patent Act* is to promote research and development for new inventions, which are useful for national agriculture and economy, and provide intellectual protection for inventors in order to prohibit others from illegally using the inventors' inventions.[301] Nevertheless, the *Thai Patent Act 1979* was criticized by trading partners of Thailand, especially the United States, because the *Patent Act* does not provide patent protection for inventions such as pharmaceutical products, and biotechnological products.[302] Therefore, the Government decided to amend the *Patent Act*

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[300] Department of Intellectual Property, "Patentable Subject Matters," online: Department of Intellectual Property <http://www.ipthailand.org/en/index2.php?option=com_content&task=view&id=103&Itemi...> [hereinafter cited as Patentable Subject Matters]. Last visit: 9 Nov.2007.
[301] *Ibid.*
[302] *Ibid.*

in 1992 due to the international pressures.[303] The *Thai Patent Act 1992* provided longer term for patent protection and broader scope of protection, compulsory licensing, and excluded certain inventions from patentability.[304] Nevertheless, the amendment of the *Patent Act* in 1992 was severely opposed because the *Act of 1992* provided the patent protection for pharmaceutical products even though the Government tried to affirm that the grant of a patent on the pharmaceutical products will not have an impact on the highly increased price of the drugs and the manufacture of the drugs.[305] The *Thai Patent Act* was amended again in 1999 after Thailand became a party to the *TRIPS Agreement*.[306]

1.1 Patentable subject matter under the *Thai Patent Act*

The *Thai Patent Act* is not different from other jurisdictions. The Department of Intellectual Property of Thailand defines the word "product" that "the products are tangible things and needs no definition. They may be made in the form of machinery, parts, devices, tool and so on."[307] The word "process" is defined to include "any method, procedure or process of producing or preserving or improving or readjusting the product including the application of such process."[308]

> Section 3 In this Act:
>
> "invention" means any innovation or invention which creates a new product or process, or any improvement of a known product or process;

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[303] *Ibid.*
[304] *Ibid.*
[305] *Ibid.*
[306] *Ibid.*
[307] *Ibid.*
[308] *Ibid.*

"design" means any form or composition of lines or colors which gives a special appearance to a product and can serve as a pattern for a product of industry or handicraft[309]

The Thai Patent Law is relatively unique when the product design is included to be patentable subject matter.[310] The grant of a patent on product design is intended to decrease the inventive idea into the external design of the product not including the whole product or process.[311]

Pursuant to s. 5 of the *Thai Patent Act*, an invention must be new, have an inventive step, and be capable of industrial application.[312] The patent criteria under the *Thai Patent Act* are also similar to other jurisdictions. Moreover, s. 35 of the *Thai Patent Act* provides the terms of patent protection for an invention for 20 years from the date of filing of the application in the country.[313] The patentees also have exclusive rights in using, selling, having the possession for sale, or importing the patented product.[314]

However, s.9 of the *Thai Patent Act* excludes certain subject matters from patentability. These excluded inventions are as follows:

1. Naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants;

2. Scientific or mathematical rules or theories;

3. Computer programs;

4. Methods of diagnosis, treatment and care of human and animal diseases;

5. Inventions that are contrary to public order or morality, public health or

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[309] *Thai Patent Act B.E. 2522 (amended B.E. 2542)*, s. 3 [hereinafter cited as *Thai Patent Act*.]
[310] Patentable Subject Matter, *supra* note 300.
[311] *Ibid.*
[312] *Thai Patent Act*, *supra* note 309 s. 5.
[313] *Ibid.*, s. 35.
[314] *Ibid.*, s. 36.

welfare.[315] (emphasis added)

S. 9 of The *Thai Patent Act* excludes animals and plants from patentability. However, non-naturally occurring microorganisms may be patentable subject matter because s. 9 of *Thai Patent Act* excludes only naturally occurring organisms from patentability. Therefore, a creation like the oncomouse could not be patented in Thailand. There is a clear intention from Parliament that animals and plants are unpatentable subject matter. This provision is intended to protect the public as much as possible. However, Thailand is a member of WTO and is obligated to implement the terms of the *TRIPS Agreement* into Thai Patent Law. Thailand was pressured to amend the *Patent Act* to be consistent with the *TRIPS Agreement*. Thailand, therefore, provided a *sui generis* system to provide intellectual protection for plant varieties by the passage of the *Plant Varieties Act*, according to the TRIPS Agreement. However, there is no *sui generis* system for genetically modified animals in Thailand. The issue of the *TRIPS Agreement* and Thai Patent Law will be discussed later.

1.2 Petty Patent[316] under the *Thai Patent Act*

The *Thai Patent Act of 1999* provides that patent applicants may apply for a petty patent, if the inventions are not qualified to apply for a regular patent.[317] Petty patents require that the invention must be new, and have industrial utility, but the petty

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[315] *Ibid.* s. 9.

[316] The term "petty patent" can be compared with an innovation patent under Australia patent law. The term "petty patent" was also used in Australia before it was changed into the term "innovation patent." (see http://www.ipaustralia.gov.au/patents/what_index.shtml).

[317] Department of Intellectual Property, "Conditions for Patentability," online: Department of Intellectual Property <http://www.ipthailand.org/en/index.php?option=com_content&task=view&id=101&Itemied=52> [hereinafter cited as Condition for Patentability]. Last visit: 9 November 2007.

patent does not require non-obviousness criteria as a regular patent. As a result, the grant of a petty patent requires certain level of inventive step of the inventions but not to the level of non-obviousness.[318] Nevertheless, an inventor cannot apply for a petty patent and a patent on the same invention.[319]

> **Section 65 bis** A petty patent may be granted for an invention in respect of which the following conditions are satisfied:
>
> (1) the invention is new;
>
> (2) it is capable of industrial application.[320]

The petty patents were contained within the *Patent Act* because statistics from the Department of Intellectual Property shown that many patentees in Thailand are foreigners.[321] The main obstruction of local inventors to receive patents is the inventive step or non-obviousness patent criterion due to the lack of advanced technology.[322] To solve this problem, the petty patents were established under the *Thai Patent Act*. Furthermore, Thailand is one of developing countries which lags behind other developed countries in technology and financial support; therefore, in order to promote useful arts and technology, petty patent was enacted to develop research and development step by step.

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[318] *Ibid.*
[319] *Ibid.*
[320] *Thai Patent Act, supra* note 309 at s. 65 ter.
[321] Conditions for Patentability, *supra* note 317.
[322] *Ibid.*

Petty patentees have exclusive rights to prevent others from making, using, and selling the inventions the same way as the patentees' exclusive rights.[323] The terms of petty patents valid for 6 years after the first filing of the petty patent application, and the petty patentees are able to extend the petty patent twice, which will last 2 years for each time.[324] The extension of petty patent must be prior to the expiry date of the petty patent 90 days.[325]

The petty patents have similar rules and regulations as the patents except the inventive step criterion. As a result, an inventor cannot apply for a petty patent on animals whether or not the animals are genetically modified animals.

2. The Patentability of Genetically Modified Animals under the Thai Patent Law

When the *Thai Patent Act* was enacted in 1979 and amended in 1992 and1999 respectively, the Thai government recognized the possibility of biotechnological inventions such as the oncomouse; however, the government did not include genetically modified animals and plants to be patentable subject matters. The grant of a patent on genetically modified animals and plants would have negative impacts on Thailand rather than positive ones. The Thai Government also realized this problem.

If genetically modified animals and plants are granted patents, there will be five disadvantages of the grant of patents to Thailand. First, the monopoly of big biological

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[323] S & I International Bangkok Office, "Laws and Regulations: Patent Law," online: S&I International Bangkok Office <http://www.s-i-asia.com/headlaw.htm. > [hereinafter cited as Patent Law]. Last visit: 10 November 2007.

[324] *Ibid.*

[325] *Ibid.*

companies will run farmers out of business.[326] Second, patented inventions mostly fall into the hands of big companies not individuals who have no potential to compete with the big companies.[327] Thai plant breeders and animal breeders are not able to compete with the big biological companies.[328] Third, the research will be profitable for the private patentees rather than the public's interest.[329] Finally, scientists in Thailand will not be able to access to invention information because of expensive licence fees.[330]

(a) Thai farmers will be run out of business

Thailand does not provide patent protection for genetically modified plants and animals, according to Dr. Jade Donavanik, due to the concern over Thai farmers who cannot afford license fees for patented inventions and the concern that these farmers cannot compete with big companies.[331] Thai farmers will be run out of business because they cannot use patented plants and animals. The patent claims cover the genetically modified mouse carrying oncogenes; therefore, the mouse is similar to regular mice except its modified oncogene. The problem is that farmers may use the genetically modified animals and plants without the knowledge that they use the patented animals and plants. Thai patent law is similar to other countries in that the infringement of patents does not require proof of the knowledge or intention of the infringers. A farmer cannot distinguish between genetically modified animals and plants from the traditional ones

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[326] Jade Donavanik, *Patents and Living Organisms,* (Bangkok, Thailand, 2007) at 101 [translated by author].
[327] *Ibid.*, at 100.
[328] *Ibid.*, at 101.
[329] *Ibid.*, at 100.
[330] *Ibid.*
[331] *Ibid.*, at 101.

because it is difficult to identify the genetically modified animals and plants with the naked eye.

This problem already occurred in *Monsanto v. Schmeiser*.[332] In *Monsanto v. Schmeiser*[333], Schmeiser, a farmer from Saskatchewan, used genetically modified canola plants and was sued by Monsanto. The Supreme Court of Canada held that Schmeiser infringed Monsanto's patent on existing modified genes and cells within the genetically modified canola plants.

According to *Monsanto*, farmers do not receive protection under the patent law. This situation may cause fears among farmers. The farmers cannot use plants or animals as before because they may infringe patentees' rights, and they cannot afford license fees. If the Thai Government grants patents on genetically modified plants and animals, Thai farmers may unintentionally violate the patentees' rights. Thai farmers have used animals and plants for centuries, so they would not recognize the change of the traditional animals and plants into the genetically modified animals and plants.

Due to this negative impact on Thai farmers, the patent law, specifically in the area of the patentability of genetically modified plants and animals, should be amended to protect the public's interest, and before permitting patents on genetically modified animals and plants, the Thai Government has to study advantages and disadvantages including the consideration of regulatory framework such as an research and experimental use exception, the innocent bystander defense, and the farmers' privilege.

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[332] *Monsanto*, *supra* note 68.
[333] *Ibid.*

Without these exceptions, Thailand is not ready to grant a patent on genetically modified animals.

On the other hand, I recommend that Canada provide patent protection for the oncomouse. The difference lies in the balancing of public interests in Thailand and Canada. Due to the advanced state of biotechnology in Canada, Canada has the capacity to produce biotechnological inventions such as the oncomouse. Therefore, Canada should grant a patent on the oncomouse and the lack of regulatory framework should not be determined to exclude the oncomouse from patentability. The regulatory framework in Canada is to protect the public safety, but the regulatory framework in Thailand protects not only the public safety but also the public interest. As a result, Thailand needs to establish a regulatory framework before the grant of a patent on the oncomouse since at this stage Thailand is not ready for the creation of the oncomouse, and it must protect the public from the adverse effects of patents, especially Thai farmers and scientists.

(b) The takeover of the transnational companies in the agriculture business

If patents on genetically modified plants and animals are granted, most of patents will fall into the hands of big foreign biological companies because Thai plant and animal breeders are not able to compete with those big companies. In Asia, many transnational companies are involved in research and experimentation on genetically modified rice.[334] For example, Syngenta, Aventis, and Monsanto conduct research and experiment on hybrid rice seeds in India, and Philippines including Thailand.[335] In Thailand, there was an economic threat from Monsanto when the Government did not grant a patent on

[334] Devlin Kuyek, et al., "Hybrid Rice in Asia: An Unfolding Threat" (March 2000), online: Grain <http://www.grain.org/briefin gs/?id=136> [hereinafter cited as Hybrid Rice]. Last visit: 13 March 2008.
[335] *Ibid.*

genetically modified plants and seeds, and to support the commercialization of genetically modified plants.[336] Monsanto threatened to move to other Asian countries such as India or Philippines because those countries provide more protection rather than Thailand.[337]

In reality, India and other countries also have activist groups that oppose the grant of patents on genetically modified plants and animals. The result of the threat from a biotechnological company such as Monsanto is losing benefits from the company; however, Thailand is still not strong enough to provide such protection. The Government decided not to allow grants of patents on genetically modified plants and animals. The problem is if Thailand retains its status not to allow genetically modified plants and animals, there will be a negative impact on Thailand's economy. The solution is to strengthen patent law while protecting the public interest.

(c) The patent on genetically modified animals will be beneficial to the private sector rather than the public

There is no patent protection for genetically modified animals in Thailand because Thailand does not have potential to conduct research on genetically modified animals due to the lack of financial support and the lag in its biotechnology development.[338]

If genetically modified plants and animals are patentable subject matter, research will be profitable for the private patent holders rather than in the public's interest. The

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[336] Kultida Samabuddhi, "Monsanto May Ditch GM Corn Investment" (29 June 2005), online: BioThai <http://www.biothai.org/cgi-bin/content/gmo/show.pl?0010 > [herinafter cited as BioThai].
[337] *Ibid.*
[338] Donavanik, *supra* note 326 at 44.

financial support from transnational companies involves publicly-based research and experimentation on genetically modified plants and animals. The Thai Government is not able to financially support the relevant research and experimentation; as a result, transnational companies will play an important role in financial support in return for obtaining patent rights on the inventions invented by the public such as universities. The problem is when transnational companies obtain patents on genetically modified plants and animals, farmers and scientists will not be able to access to technology because of exorbitant license fees.[339] If the Government does not provide protection for farmers and scientists, the patent law would become advantageous to the transnational companies rather than the public sector in Thailand.[340]

Nevertheless, certain transnational companies such as Monsanto and Syngenta made an effort to provide access to advanced technology in the case of golden rice due to a concern over the access to technology in developing countries.[341] Golden Rice is rice that has been genetically modified to contain pro-vitamin A.[342] Golden Rice containing pro-vitamin A is useful for preventing impaired immune systems, blindness in children and some fatal diseases.[343] Golden Rice was patented by many companies. The problem is the access to technology due to expensive license fees.[344] Therefore, many companies such as Syngenta have collaborated with the Golden Rice Humanitarian Board, which

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[339] *Ibid.*, at 100.
[340] *Ibid.*
[341] Justin Gillis, "Monsanto Offers Patent Waiver," online: Grain < http://www.grain.org/bio-ipr/?id=175> Last visit: 16 August 2008.
[342] Golden Rice, "Golden Rice is a part of the solution", online: Golden Rice< http://www.goldenrice.org/index.html>. [hereinafter cited as Golden Rice]. Last visit: 16 August 2008.
[343] *Ibid.*
[344] *Ibid.*

was established to provide free access to golden rice for developing countries under the "Humanitarian Golden Rice Project," [345] to provide golden rice for developing countries for free of charge in order to help people, particularly children, who are malnutrition in developing countries.[346] The example of golden rice solves the problem of the bar to the access technology. If the transnational companies maintain the position as in the golden rice scenario for other patented inventions, I believe that the reluctance over the grant of patents over biotechnological inventions in developing countries will decrease, and the concern about the access to technology will be solved. Moreover, there might be free flow of scientific information since scientists will be able to work freely without the fear of patent infringement.

(d) The obstruction of the access advanced biotechnological technology

Scientists in Thailand might not be able to access advanced biotechnology and other new technologies because of the expensive license fees relating to patents of inventions. Due to the lack of the research and experimental use exception, scientists fear that if genetically modified plants and animals become patentable subject matters, they will be barred from access to the patented inventions in order to study and develop the inventions. Scientists cannot afford expensive license fees on the patented inventions. For example, in 1993, when Thailand did not have advanced technology to conduct research and experiment on marine fungi strains, Thailand lent fungi strains to Britain's Portsmouth University to study the fungi strains and develop medicine from the

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[345] Ingo Protrykus, "Experience from the Humanitarian Golden Rice Project: Extreme Precautionary Regulation Prevents Use of Green Biotechnology in Public Projects" , online: Agbioworld < http://www.agbioworld.org/biotech-info/articles/biotech-art/potrykus.html>. Last visit: 16 August 2008.
[346] Golden Rice, *supra* note 342.

strains.[347] If research and experimentation on the marine fungi strains is successful, the marine fungi strains are expected to be an important ingredient in treating serious diseases such as cancer and AIDS.[348] Now, Thailand is able to conduct research on the marine fungi strains; therefore, Thailand recalled the strains from Britain.[349] Thailand fears that if British pharmaceutical companies receive patents on the fungi strains for their medicine, Thai scientists will not be able to access to the fungi strains and develop them into medicine in the future.[350] However, Britain has not returned the marine fungi strains, and the Thai Government still has made an effort to negotiate to receive the fungi strains back.[351]

3. Patents on biological inventions

Under *Thai patent law,* microorganisms existing naturally, plants, and animals including parts of plants or animals are unpatentable subject matter.[352] Moreover, cells, genes, and modified genes and cells are excluded from patentability.[353] Nevertheless, nucleic acid is a patentable subject matter as a chemical substance pursuant to the interpretation of the Thai patent law.[354] As a result, cells, genes, DNA construct, molecular markers, vector, isolated nucleic acid molecule and Expressed Sequence Tag (EST) are patentable subject matters because they are chemical substances, and they are

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[347] Prangtip Daorueng. "Thailand: Tussle Over Fungi Strains Brings Painful Lessons" (11 December 2003), online: BioThai < http://www.biothai.org/cgi-bin/content/biopiracy/show.pl?0001> [hereinafter cited as Fungi Strains]. Last visit: 14 February, 2008.
[348] *Ibid.*
[349] *Ibid.*
[350] *Ibid.*
[351] *Ibid.*
[352] *Thai Patent Act*, *supra* note 309 s.9.
[353] Donavanik, *supra* note 326 at 11.
[354] *Ibid.*

interpreted not to be parts of plants or animals.[355] Even though genetically modified plants and animals are excluded from patentability, modified genes and cells are patentable subject matters as chemical substances not because they are part of plants or animals.[356]

In the application of the patents on modified genes and cells under Thai patent law, the problem may rise the same way as in *Monsanto* case in that patents on modified genes and cells existing within the genetically modified plants and animals are patentable subject matter even though the plants or animals are unpatentable subject matter.[357] There will be two problems from this situation as follows:

(a) The infringement of the patentees' rights on the use of genetically modified animals and plants without the knowledge that the modified genes and cells within the plants are patentable subject matter.

Farmers may plant the plants consisting of patented genes and cells with or without knowledge that there is patent protection for genes and cells. Consequently, farmers will infringe patentees' rights, regardless of whether the farmers intend or do not intend to use the patented invention.[358]

(b) The blow-by seeds situation

If seeds of genetically modified plants blow into an innocent farmer's land without his/her knowledge, the farmer may infringe the patentees' rights by using the

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[355] *Ibid.*
[356] *Ibid.*, at 12.
[357] *Ibid.*, at 32.
[358] *Ibid.*, at 33.

patented products without permission from patentees.[359] This case is the same scenario as in *Schmeiser* when farmers grow plants consisting of modified genes and cells without recognizing that they are growing genetically modified plants and that they are infringing the patentees' rights on the genetically modified plants.

One response available to farmers is to sue the patentees for failing to provide adequate equipment to prevent the spreading of their inventions, so their inventions have contaminated the farmers' plants.[360] This concern is increased in the area of organic farms since organic farmers are greatly affected by the spread-out of genetically modified plants and animals onto their organic farms.

Besides the problem of the infringement of patentees' rights in modified genes in Thailand, another problem is that the inventor of genetically modified inventions or genes did not apply for a patent for the invention in Thailand, but the inventor already applied for a patent in other countries.[361] If the countries in which the inventor had a patent on genetically modified plants or animals are trading partners of Thailand, there will be a problem that persons exporting products from Thailand might infringe patentee's rights in those countries and be denied from exporting.[362] Farmers often do not know that they infringed patentee's rights and they do not have knowledge about the patented invention; as a consequence, these farmers are in weak position to protect themselves.[363]

4. *TRIPS Agreement* and Thailand

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[359] *Ibid.*, at 34.
[360] *Ibid.*, at 35.
[361] *Ibid.*, at 34.
[362] *Ibid.*
[363] *Ibid.*

Thailand is one of WTO Members; as a consequence, Thailand is obliged to follow the *TRIPS Agreement*. Article 27.3 (b) of *TRIPS Agreement* recognizes the patentability of plant and animal life forms unless there is a specific regulation excluding such patents. In Thailand, there is no patent protection for plant and animal life forms. Thailand wants to protect farmers and local people from patentees' exclusive rights in plant and animal life forms. However, the Thai Government has established the *Plant Varieties Act B. E. 2542* in order to be consistent with Article 27.3 (b).[364] Thailand tries to retain the *status quo* because the grant of a patent on genetically modified plants and animals is not beneficial to Thailand. Thailand was obliged to implement Article 27.3 (b) into *Thai Patent Act* by January, 1 2000.[365] Nevertheless, there was no implementation of the *TRIPS Agreement* within *Thai Patent Act* because Thailand still has weak intellectual property protection system. Moreover, concerns have been voiced about Article 27.3 (b) of *TRIPS Agreement* by many developing countries including Thailand. If there is a definite agreement among WTO members, the implementation of Article 27.3 (b) of *TRIPS Agreement* into *Thai Patent Act* will be much clearer. In the current situation, Thailand will take advantage of being a developing country along with other developing countries such as India and African countries in opposing the patent on the genetically modified plants and animals according to Article 27.3 (b) of *TRIPS Agreement*.

In *Harvard College*, Bastarache J. opined that the specific exception in *TRIPS Agreement* merely indicates that the distinction between higher life forms and lower life

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[364] Donavanik, *supra* note 326 at 43.

[365] Third World Network, "Joint NGO Statement on the Review of Article 27.3 (b) of the TRIPS Agreement," online: Third World Network < http://www.twnside.org.sg/title/joint2.htm>. Last visit: 10 November 2007.

forms is generally recognized by other Members.[366] Canada could retain the *status quo* in that higher life forms are not patentable subject matter due to the interpretation of Bastarache J., and Canada did not violate *TRIPS Agreement*.[367] Likewise, Thailand could take the Canadian perspective on the exclusion of genetically modified plants and animals from patentability. Thailand does not provide patent protection for the inventions like the oncomouse because Thailand wants to retain the *status quo*, and the above reasons demonstrate that Thailand wants to protect farmers and local people.

The rejection of *TRIPS Agreement* provision is not a solution. There are many other countries which have agreed to implement *TRIPS Agreement*. Thailand should prepare for the grant of a patent on genetically modified plants and animals by providing a regulatory framework to protect the public's interest. However, Thailand is one of the developing countries; therefore, it is difficult to provide the same patent protection for genetically modified plants and animals as other developed countries because Thailand has much less power of negotiation. Thailand still needs time to advance patent law and technology. The grant of patents on genetically modified plants and animals in this current situation will have negative effects on Thailand rather than positive ones.

Conclusion

Genetically modified plants and animals are not recognized to be patentable subject matters under the current *Thai Patent Act*. The Thai Government explicitly intends to exclude plants and animals from patentability by containing the exclusion

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[366] *Harvard College, supra* note 4 at para. 205.
[367] *Ibid.*

within the provisions of the *Patent Act*. The main reason for the exclusion of the patents on plants and animals is to protect the public interest respecting access to technology. Furthermore, the disadvantages of the grant of a patent on genetically modified plants and animals cannot currently be managed because of the lack of regulatory framework under the *Thai Patent Act*. If the Thai Government decides to permit grants of patents on genetically modified plants and animals, a regulatory framework should be established to protect the public's interest. The exclusion of plants and animals from patentability also leads to the problem of the violation of the *TRIPS Agreement*, to which Thailand is a party. However, the implementation of the *TRIPS Agreement* is still in dispute among developing countries. Thailand wants to remain *status quo* in the denial of the grant of a patent on genetically modified plants and animals. However, the denial of patents of genetically modified plants and animals is not a solution to protect the public's interests. The solution is to strengthen the patent system by providing an appropriate regulatory framework to protect the public's interest while permitting grants of patents on genetically modified plants and animals.

Conclusion

There are arguments both for and against the patentability of higher life forms such as the genetically modified animals or the oncomouse. Most commentators, including the CBAC, are likely to support the amendment of the *Canadian Patent Act* to permit the patentability of the oncomouse and similar creations as a "compositions of matter".

Dissenting in *Harvard College*, Binnie J. argued that Canada should provide patent protection for the oncomouse due to economic reasons and international pressures. More importantly, Binnie J. argued that the oncomouse could fit within the definition of 'composition of matter' because Harvard researchers have invented a new genetically modified mouse and the oncomouse meets the patent criteria. Moreover, the *sui generis* system was raised to consider whether it is suitable to protect the oncomouse. The *sui generis* system might not be useful or become obsolete subsequently because new technologies always develop, and the law cannot follow every new technology. Therefore, the *Patent Act* might be the proper solution for the patents of higher life forms.

With respect, I disagree with the majority's opinion in that the oncomouse was not patentable subject matter under the *Patent Act* because the mouse fits the definition of "composition of matters" since the mouse is genetically engineered to be composed of oncogenes (in addition to other genetic material), and the mouse also meets the patent criteria. The majority also argued that Parliament did not intend to include the oncomouse to be patentable subject matter because of the lack of regulatory framework; therefore the Patent Act is 'ill-equipped' to deal with the patentability of higher life forms.

While the fertilized eggs are patentable subject matters, the whole mouse cannot be patented even though the mouse is the result of the fertilized eggs, so why should the patent not apply to the oncomouse? The oncomouse should be granted a patent if it meets patent criteria, and a regulatory framework such as the research and experimental use exception, innocent bystander defense, a farmer's privilege and 'ordre public' and morality should be considered to protect the public safety.

In Thailand, due to the lack of capacity to create the genetically modified animals, the grant of patents on genetically modified animals is not a discussed issue. Moreover, *Thai Patent Act* excludes plants and animals from patentability. Thailand does not want to provide patent protection for genetically modified animals because of the fear of the access to advanced technology and patent infringement, if there is no patent waiver from patentees such as in the golden rice case. To solve this problem, a regulatory framework is a solution for Thailand to balance the patentees' rights and the public interest. I recommend that Thailand should establish a regulatory framework before the grant of patents on genetically modified animals because the need to protect the public interest in developing countries is different than in developed countries, particularly because Thailand lags behind developed countries in advanced technology.

To conclude, Canada should grant a patent on the oncomouse as a "composition of matter" according to the interpretation of the word from the dissent in *Harvard College*. If the court did not deny interpreting the words of the Act, the *Patent Act* would not be 'ill-equipped" and the *sui generis* system for the oncomouse will be unnecessary. However, the issue of regulatory framework needs to be considered but it should not

affect the grant of a patent on the oncomouse because the need for the protection of the public interest in Canada is different than in Thailand because of the relatively high stage of technological advancement in Canada.

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